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APPENDIX

In the Supreme Court of the United States

OCTOBER TERM, 1979

Nos. 78-911 and 78-1036

INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
Petitioner

—*v.*—

AMERICAN PETROLEUM INSTITUTE, ET AL.

RAY MARSHALL, SECRETARY OF LABOR,
Petitioner

—*v.*—

AMERICAN PETROLEUM INSTITUTE, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

PETITIONS FOR A WRIT OF CERTIORARI FILED DECEMBER 7, 1978 (NO. 78-911) AND DECEMBER 26, 1978 (NO. 78-1036)
CERTIORARI GRANTED FEBRUARY 21, 1979

In the Supreme Court of the United States

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INDUSTRIAL UNION DEPARTMENT, AFL-CIO,
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Petitioner

—*v.*—

AMERICAN PETROLEUM INSTITUTE, ET AL.

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

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AMERICAN PETROLEUM INSTITUTE ET AL. v. OSHA ET AL., NO. 78-1253

Feb. 2, 1978 Petition for review

March 13, 1978 Order granting motion of Manufacturing Chemists Association, The American Iron And Steel Institute, and Chemical Specialties Manufacturers for leave to intervene. (LRM) (Also filed in 78-1257).

March 21, 1978 Order granting motion of the Industrial Union Department, AFL-CIO to intervene (Also filed in 78-1257).

April 18, 1978 Order continuing temporary stay entered on 3/13/78 pending disposition of petitions for review. Further granting motion of Independent Petroleum Association of America for leave to intervene. Further petitioners' motion to consolidate is granted.[*] Further the motion to dismiss petition of review filed by Am. Petroleum in No. 77-1973, API, et al v. OSHRC is carried with the case. Further the motion to correct captions in 78-1253 and 78-1257 is granted.

June 22, 1978 Case argued.

June 23, 1978 Respondents' letter dtd 6/22/78 with copy of amendments to the benzene standard issued June 27, 1978. (CE) (Also filed in consolidated cases).

June 30, 1978 Petitioners' letter dtd 6/30/78 with "producer" petitioners' supplemental memorandum which addresses amendment to benzene standard and copy of Federal Register notice announcing amendment. (CE) (Also filed in consolidated cases).

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[*] This order consolidated cases nos. 78-1253, 1257, 1486, 1676, 1677, 1707, 1745, and any other cases seeking review of the benzene standard later transferred to the Fifth Circuit.

July 7, 1978 Order granting motion of petitioners, the Rubber Manufacturers Association, Inc., et al and the Armstrong Rubber Company, et al. to filed amended petitions for review. (JPC-CC-GBT).

July 11, 1978 Filing Secretary of Labor's motion to adjourn present supplemental briefing schedule and to set new briefing schedule on the merits of the amendment to the benzene standard.

July 12, 1978 Filing Response of Rubber Companies and Du Pont in opposition to motion to adjourn briefing schedule, etc.

July 14, 1978 Order denying the Secretary of Labor's motion to adjourn present supplemental briefing schedule. Court does not desire briefs designed to enable it to reach the merits of the new standards. (CC) (Also filed in consolidated cases).

August 4, 1978 Filing Motion of Manufacturing Chemists Association petitioner in No. 78-1988, to file amended petition for review. (Filed in consolidated cases).

August 4, 1978 Filing contingent motion of Manufacturing Chemists Association to defer briefing dates on the merits of the liquid mixture exemption amendment to the benzene standard. (Also filed in consolidated cases).

August 7, 1978 Filing motion of the American Iron and Steel Institute to file amended petition for review in No. 78-1745. (Also filed in consolidated cases).

August 7, 1978 Filing motion of the American Iron and Steel Institute to defer briefing on the merits of the liquid mixture exemption amendment to the benzene standard (Also filed in consolidated cases).

August 11, 1978 Order granting motion of the Manufacturing Chemists Association to file an amended petition for review; further order granting the contingent motion of Manufacturing Chemists Association to defer briefing on the merits of the liquid mixture exemption amendment to the benzene standard (CC) (Also filed in consolidated cases).

August 11, 1978 Order granting motion of the American Iron and Steel Institute to file amended petition for review in No. 78-1745; further order granting motion of American Iron and Steel Institute to defer briefing on the merits of the liquid mixture exemption amendment to the benzene standard. (CC) (Also filed in consolidated cases).

August 14, 1978 Motion of E. I. Du Pont de Nemours & Co. to file amended petition for review. (Also filed in consolidated cases).

August 18, 1978 Order granting motion of E.I. DuPont de Nemours and Company to file an amended petition for review.

October 5, 1978 Opinion and Judgment.

THE AMERICAN PETROLEUM INSTITUTE AND THE NATIONAL PETROLEUM REFINERS, ET AL. v. OSHA ET AL., NO. 78-1257

[The relevant docket entries for No. 78-1257 are the same as for No. 78-1253 except that the petition for review was filed a day later (February 3, 1978) and the docket for No. 78-1257 omits the entries for April 18 and July 7, 1978, shown above for No. 78-1253.]

THE RUBBER MANUFACTUERS ASSOCIATION, INC., ET AL. v. EULA BINGHAM, ET AL., NO. 78-1486

March 6, 1978 Petition to review and set aside an order of the Assistant Secretary of Labor for OSHA filed [in the Sixth Circuit, No. 78-3114].

March 9, 1978 Order granting motion of petitioners to transfer this cause to the United States Court of Appeals for the Fifth Circuit.

[After transfer, the Fifth Circuit renumbered the case No. 78-1486 and made the following entries:]

March 13, 1978 Filing order of the Sixth Circuit transferring their docket No. 78-3114 to the 5th Circuit.

April 11, 1978 Order granting motion of the Industrial Union Department, AFL-CIO, to intervene. (LRM) (Also filed in 78-1676, 78-1677, and 78-1707).

May 5, 1978 Filing respondents' motion to reschedule argument. Denied JPC.

June 22, 1978 Case argued.

June 23, 1978 Filing respondents' letter dtd 6/22/78 with copy of amendments to the benzene standard issued June 27, 1978. (CE) (Also filed in consolidated cases).

June 27, 1978 Filing motion of petitioners in Nos. 78-1486 and 78-1677 to file amended petitions for review.

June 30, 1978 Filing petitioners' letter dtd 6/30/78 with "producer" petitioners' supplemental memorandum which addresses amendment to benzene standard and copy of Federal Register Notice announcing amendment. (CE) (Also filed in consolidated cases).

July 7, 1978 Order granting motion of petitioners, the Rubber Manufactuers Association, Inc, et al, and the Armstrong Rubber Company et al, to file amended petitions for review. (JPC-CC-GBT) (Also filed in 78-1677).

July 11, 1978 Filing Secretary of Labor's motion to adjourn present supplemental briefing schedule, and to set new briefing schedule on the merits of the amendment to the benzene standard.

July 14, 1978 Order denying the Secretary of Labor's motion to adjourn present supplemental briefing schedule. Court does not desire briefs designed to enable it to reach the merits of the new standards. (CC).

July 24, 1978 Order granting motion of Chemical Specialities Manufacturers Association for leave to intervene (CC).

August 4, 1978 Filing motion of Manufacturing Chemists Association, petitoner in No. 78-1988, to file amended petition for review. (Also filed in consolidated cases).

August 4, 1978 Filing contingent motion of Manufacturing Chemists Association to defer briefing dates on the merits of the liquid mixture exemption amendment to the benzene standard. (Also filed in consolidated cases).

August 7, 1978 Filing motion of the American Iron and Steel Institute to file amended petition for review in No. 78-1745. (Also filed in consolidated cases).

August 7, 1978 Filing motion of American Iron and Steel Institute to defer briefing on the merits of the liquid mixture exemption amendment to the benzene standard. (Also filed in consolidated cases).

August 11, 1978 Order granting motion of the Manufacturing Chemists Association to file an amended petition for review; further order granting the contingent motion of Manufacturing Chemists Association to defer briefing on the merits of the liquid mixture amendment to the benzene standard. (CC) (Also filed in consolidated cases).

August 11, 1978 Order granting motion of the American Iron and Steel institute to file amended petition for review in No. 78-1745; further order granting motion of American Iron and Steel Institute to defer briefing on the merits of the liquid mixture exemption amendment to the benzene standard. (CC) (Also filed in consolidated cases).

August 18, 1978 Order granting motion of E.I. duPont de Nemours and Company to file an amended petition for review. (Also filed in consolidated cases).

October 5, 1978 Opinion and Judgment.

E. I. DU PONT DE NEMOURS & CO. v. OSHA ET AL., NO. 78-1676

March 10, 1978 Petition for review of an order of the Occupational Safety and Health Administration, U.S. Department of Labor, received March 10, 1978, filed [in the Third Circuit, No. 78-1290]. (10 cc) Service attached.

March 31, 1978 Order (Aldisert and Adams, C.J.) granting the motions by petitioner for expedited consideration of "petitioner's Motion for Transfer" *and* to transfer Petition for Review to the United States Court of Appeals for the Fifth Circuit filed.

[After transfer, the Fifth Circuit renumbered the case No. 78-1676 and made the following entries:]

April 3, 1978 Filing Order of the Third Circuit transferring their docket No. 78-1290 to the 5th Circuit.

April 11, 1978 Order granting motion of the Industrial Union Department, AFL-CIO, to intervene. (LRM). (Also filed 78-1486, 78-1677 & 78-1707).

May 5, 1978 Filing Respondents' motion to reschedule argument. Denied JPC.

June 22, 1978 Case argued.

June 23, 1978 Filing respondents' letter dtd 6/22/78 with copy of amendments to the benzene standard issued June 27, 1978. (CE) (Also filed in consolidated cases).

June 30, 1978 Filing petitioner's letter dtd 6/30/78 with "producer" petitioners' supplemental memorandum which addresses amendment to benzene standard and copy of Federal Register Notice announcing amendment. (CE) (Also filed in consolidated cases).

July 11, 1978 Filing Secretary of Labor's motion to adjourn present supplemental briefing schedule, and to set new briefing schedule on the merits of the amendment to the benzene standard.

July 14, 1978 Order denying the Secretary of Labor's motion to adjourn present supplemental briefing schedule. Court does not desire briefs designed to enable it to reach the merits of the new standards. (CC) (Also filed in consolidated cases).

August 4, 1978 Filing motion of Manufacturing Chemists Association, petitioner in No. 78-1988, to file amended petition for review. (Also filed in consolidated cases).

August 4, 1978 Filing contingent motion of Manufacturing Chemists Association to defer briefing dates on the merits of the liquid mixture exemption amendment to the benzene standard. (Also filed in consolidated cases).

August 7, 1978 Filing motion of the American Iron and Steel Institute to file amended petition for review in No. 78-1745. (also filed in consolidated cases).

August 7, 1978 Filing motion of American Iron and Steel Institute to defer briefing schedule on the merits of the liquid mixture exemption to the benzene standard. (Also filed in consolidated cases).

August 11, 1978 Order granting motion of the Manufacturing Chemists Association to file an amended petition for review; further order granting the contingent motion of Manufacturing Chemists Association to defer briefing on the merits of the liquid mixture exemption amendment to the benzene standard (CC) (Also filed in consolidated cases).

August 11, 1978 Order granting motion of the American Iron and Steel Institute to file amended petition for review in No. 78-1745; further order granting motion of American Iron and Steel Institute to defer briefing on the merits of the liquid mixture exemption amendment to the benzene standard (CC) (Also filed in consolidated cases).

August 18, 1978 Order granting motion of E.I. Du Pont de Nemours & Co. to file an amended petition for review. (Also filed in consolidated cases).

October 5, 1978 Opinion and Judgment.

THE ARMSTRONG RUBBER COMPANY AND UNIROYAL, INC. v. EULA BINGHAM, ET AL., NO. 78-1677

March 6, 1978 Filed Petition for review [in Second Circuit No. 78-4034].

March 27, 1978 Filed Order granting motion to transfer to the United States Court of Appeals for the Fifth Circuit.

[After transfer, the Fifth Circuit renumbered the case No. 78-1677 and made the following entries:]

April 3, 1978 Filing Order of the Second Circuit transferring their docket No. 78-4034 to the 5th Circuit.

[The remainder of the relevant docket entries made by the Fifth Circuit in No. 78-1677 are identical to those beginning April 11, 1978, by the Fifth Circuit in No. 78-1676.]

INDEPENDENT PETROLEUM ASSOCIATION OF AMERICA v. OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, U.S. DEPARTMENT OF LABOR, ET AL., NO. 78-1707

1978 Petition for review filed.

[The remainder of the relevant entries for No. 78-1707 are identical to those shown for No. 78-1676 beginning with the entry for April 11, 1978, with the exception that the docket in No. 78-1707 omits the entry for July 11, 1978.]

AMERICAN IRON AND STEEL INSTITUTE, ET AL. v. OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, U.S. DEPARTMENT OF LABOR, ET AL., NO. 78-1745

April 3, 1978 Petition for Review of an order of the Occupational Safety and Health Administration United States Department of Labor, received April 3, 1978, filed [in the Third Circuit as No. 78-1388]. (6 cc) Service attached.

April 7, 1978 Order (*Aldisert* and Adams, C.J.) granting petitioners' motion for transfer of Petition for Review to the United States Court of Appeals for the Fifth Circuit, filed.

[After transfer, the Fifth Circuit renumbered the case No. 78-1745 and made the following entries:]

April 10, 1978 Filing Order of the Third Circuit transferring their docket no. 78-1388 to the 5th Circuit.

[The remainder of the relevant entries for No. 78-1745 are identical to those shown for No. 78-1676, beginning with the entry for May 5, 1978, with the exception that the docket in No. 78-1745 omits the entry for July 11, 1978.]

MANUFACTURING CHEMISTS ASSOCIATION v. OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, ET AL., NO. 78-1988

March 30, 1978 Petitioner's petition for review of an order of the Occupational Safety and Health Administration (m-30) [filed in the United States Court of Appeals for the District of Columbia Circuit, No. 1287].

May 5, 1978 Per curiam order granting petitioner's motion to transfer this case to the Fifth Circuit; Bazelon and Leventhal, CJ's.

[After transfer, the Fifth Circuit renumbered the case No. 78-1988 and made the following entries:]

May 8, 1978 Filing order of the District of Columbia Circuit transferring their docket No. 78-1287 to the Fifth Circuit.

June 22, 1978 Case argued.

June 30, 1978 Filing petitioners' letter dtd 6/30/78 with "producers" petitioners' supplemental memorandum which addresses amendment to benzene standard and copy of Federal Register Notice announcing amendment. (CE) (Also filed in consolidated cases.)

July 14, 1978 Order denying the Secretary of Labor's motion to adjourn present supplemental briefing schedule. Court does not desire briefs designed to enable it to reach the merits of the new standards. (CC) (Also filed in consolidated cases).

[The remainder of the entries for No. 78-1988 are identical to those beginning with August 4, 1978, for No. 78-1676, except that the docket for No. 78-1988 omits the entry for August 11, 1978, granting motion of AISI to file amended petition and to defer briefing on amendment.]

INDEPENDENT PETROLEUM ASSOCIATION OF AMERICA v. OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION ET AL., NO. 78-1989

April 4, 1978 Petitioners' petition for review of an order of the OSHA (m-4) [filed in the United States Court of Appeals for the District of Columbia Circuit, No. 1308].

May 3, 1978 Per Curiam Order granting Petitioners' motion for transfer and this case is transferred to the Fifth Circuit: Bazelon and Leventhal, CJ's.

[After transfer, the Fifth Circuit renumbered the case No. 78-1989, and made the following entries:]

May 8, 1978 Filing Order of the District of Columbia Circuit transferring their docket no. 78-1308 to the 5th Circuit.

June 22, 1978 Case argued.

July 14, 1978 Order denying the Secretary of Labor's motion to adjourn present supplemental briefing schedule. Court does not desire briefs designed to enable it to reach the merits of the new standards. (CC) (Also filed in consolidated cases).

August 18, 1978 Order granting motion of E.I. Du Pont de Nemours & Co. to file an amended petition for review. (Also filed in consolidated cases)

October 5, 1978 Opinion and Judgment.

November 1, 1978 Order consolidating this appeal with 78-1253, et al (CC).

INDUSTRIAL UNION DEPARTMENT, AFL-CIO v. DR. EULA BINGHAM, ET AL., NO. 78-2642

July 11, 1978 Petitioner's petition for review of order of the Dept. of Labor (p-10) [filed in the United States Court of Appeals for the District of Columbia Circuit, No. 1644].

July 26, 1978 Per curiam order granting petitioner's motion to transfer and this case is to be transferred to the USCA for the 5th Circuit as promptly as the business of office permits; CJ Wright and McGowan, CJ.

[After transfer, the Fifth Circuit renumbered the case No. 78-2642 and made the following entries:]

August 1, 1978 Filing order of the District of Columbia Circuit transferring their docket no. 78-1644 to the 5th Circuit.

August 18, 1978 Order granting motion of E. I. Du Pont de Nemours & Co. to file an amended petition for review. (Also filed in consolidated cases).

October 5, 1978 Opinion and judgment.

November 1, 1978 Order consolidating this appeal with 78-1253 et al (CC).

THE AMERICAN PETROLEUM INSTITUTE AND THE NATIONAL PETROLEUM REFINERS ASSOCIATION, ET AL. v. OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION UNITED STATES DEPARTMENT OF LABOR, ET AL, NO. 78-2779

August 18, 1978 Petition for review filed.

October 5, 1978 Opinion and judgment.

THE ADHESIVE AND SEALANT COUNCIL, INC. v. EULA BINGHAM, ET AL, NO. 78-3023

[This case was filed in the Fourth Circuit on August 18, 1978, and transferred to the Fifth Circuit on September 11, 1978. The record does not include the Fourth Circuit's docket entries but does disclose the filing and transfer dates. After transfer, the Fifth Circuit renumbered the case No. 78-3023, and made the following docket entries:]

Sept. 18, 1978 Filing Order of the Fourth Circuit transferring their docket no. 78-1544 to the Fifth Circuit.

October 5, 1978 Opinion and Judgment.

November 1, 1978 Order consolidating this appeal with 78-1253 et al. (CC).

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 78-1253

THE AMERICAN PETROLEUM INSTITUTE, ET AL.,
PETITIONERS

v.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION,
RESPONDENTS

PETITION FOR REVIEW

Pursuant to Section 6(f) of the Occupational Safety and Health Act of 1970, 29 U.S.C. § 655(f), The American Petroleum Institute, the National Petroleum Refiners Association on behalf of their respective members, and American Petrofina, Incorporated, Cities Service Company, Continental Oil Company, Delta Oil Company, Exxon Corporation, Gulf Oil Company, Husky Oil Company, Marathon Oil Company, Mobil Oil Corporation, Phillips Petroleum Company, Shell Oil Company, South Hampton Oil Company, Standard Oil Company (Indiana), The Standard Oil Company (Ohio), Sun Oil Company of Pennsylvania, Sun Oil Company of Delaware, Texaco Inc., Union Oil Company of California, U.S.A. Petrochem Corporation, and Williams Pipe Line Company, hereby challenge the validity of, and petition this Court for review of, the Permanent Standard for Occupational Exposure to Benzene released by the Occupational Safety and Health Administration, Department of Labor, on February 2, 1978.

The Permanent Standard for Occupational Exposure to Benzene challenged by this Petition supplants and replaces the Emergency Temporary Standard for Occupational Exposure to Benzene (42 Fed. Reg. 22516) previously challenged by the same petitioners in *American Petroleum Institute, et al.* v. *OSHA, et al.*, No. 77-1973, presently pending before this Court.

By this Petition, the above captioned petitioners also challenge OSHA's procedural regulations dealing with the official time for issuance of agency actions (29 C.F.R. § 1911.18(d), 42 Fed. Reg. 65166) on the ground that such regulations may be invalid and inconsistent with the D.C. Circuit's opinion in *Industrial Union Dept. AFL-CIO, et al.* v. *Bingham, et al.*, Nos. 77-1395, 77-1516 which retransferred *API, et al.* v. *OSHA, et al.* (No. 77-1973) to this Court.

Respectfully submitted,

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February 2, 1978.

[The following document was appended to the agency brief in the court of appeals]

CARCINOGEN ASSESSMENT GROUP'S PRELIMINARY REPORT ON POPULATION RISK TO AMBIENT BENZENE EXPOSURES

This document is being released by EPA for external review

ROY E. ALBERT, M. D.
Chairman

PARTICIPATING MEMBERS

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PRELIMINARY ESTIMATE OF POPULATION RISK TO AMBIENT BENZENE EXPOSURES

I *Summary*

There is substantial epidemiological evidence that benzene is a human leukemogen. However, no validated animal model has yet been developed for benzene as a carcinogen. There are several large series of case reports indicating a high risk of leukemia in individuals who developed aplastic anemia consequent to benzene exposure. In addition there are a number of epidemiological studies in the rubber and shoe industries that demonstrate an excess risk of leukemia. From the standpoint of making quantitative estimates of the leukemia risk associated with current general population exposures to benzene in the United States there are only two epidemiological studies that provide some estimates of both exposure to benzene and data on the occurence of leukemia. These studies are by Infante (3) and by Ott, et al. (5).

The Infante study, which showed an excess incidence of leukemia, is not yet completely analyzed. Hence, some assumptions have had to be made about the average duration and magnitude of exposures. For this reason, this report should be considered as preliminary. The Ott study indicated no excess leukemia risk with relatively well-documented exposures.

The results of the Infante study were used as the basis for an extrapolation of the leukemia risk to the low levels of general population exposure, which averages one part per billion (4). A linear non-threshhold model was used for the extrapolation; such a model is expected to give an upper limit to the estimated risk. Using this extrapolation model, and using the leukemia rates observed in the cohort of workers exposed to benzene over a period of about 30 years (in the Infante study), we estimated that the number of cases of acute myelogenous and myonocytic [2] leukemia per year in the general population

due to ambient atmospheric benzene is somewhere between 30 and 80 cases. The lifetime risk to an individual continually exposed to benzene at a level of 1 ppb is estimated to be between 10^{-5} and 2.5 x 10^{-5}, depending on which exposure assumptions are made in the Infante study. The risk from individual sources of benzene emissions ranges from about 10^{-6} to 5 x 10^{-5}. The Ott study, which reported no excess leukemia risk, is consistent with the Infante study on statistical grounds given their relative exposures. However, the negative results of the Ott study suggest that the level of calculated risk in the general population is not likely to be higher than 10^{-5} to 2.5 x 10^{-5}, but it could be lower.

[3] II *Introduction*

The Carcinogen Assessment Group (CAG) has been asked by the Office of Air Quality Planning and Standards (OAQPS) to estimate the carcinogenic risk to the United States population of ambient benzene concentrations. This type of information is useful in judging the overall contribution of benzene emissions to the national rates of cancer mortality, and will be used by OAQPS in the decision whether to regulate benzene.

As the primary basis for this estimation the CAG is using the Infante (Infante, et al. 1977) mortality study of workers exposed to benzene in the production of a natural rubber cast film product. The reasons for this choice are: (1) the worker exposures are said to have been almost exclusively restricted to benzene, since it is used throughout the plant as the principal solvent in all major processes; (2) the individuals in the cohort all worked before 1950 and were followed until 1975, thus allowing long latency diseases to be observed and (3) acute myelogenous leukemia was observed, which is the same cell type of leukemia observed in other studies where workers have had known benzene exposures. The disadvantages of relying on this study for determining general population risks are (1) the authors essentially give no estimate of worker exposures except to say that the levels were less than the prevailing recommended occupational limits at the time various monitoring surveys were made; (2) the cohort studied actually worked at two separate plants (Akron and St. Mary's, Ohio). Air monitoring information in the former plant is almost non-existent (Baier, 1977), and therefore the exposure to half of the members of the cohort is almost completely unknown. However, it is known (Young, 1977) that the crude rates (leukemia cases/total people in the cohort) are similar in the two [4] locations; (3) Warren et al. (1977) have claimed that over 400 workers known to be exposed to low benzene levels were deliberately excluded from the cohort.

In spite of these difficulties the Infante study is the only one currently available which reports an excess rate of leukemia among benzene-exposed populations. Another occupational study (Ott, et al. 1977) of workers exposed to benzene has documented the exposures relatively well and reports no excess leukemia risk. The risk estimates based on Infante's study are used to calculate the number of cases expected in the cohort examined by Ott, et al. If this is not significantly different than the observed number of cases, the estimates are not grossly in error. A more complete evaluation of the Infante study will be possible after the authors have made a final evaluation of their data.

III. *Description of Infante Study*

In a retrospective study of mortality among a cohort of 748 white male workers in two Ohio plants manufacturing a natural rubber cast film product, Infante, et al. (1977) observed a statistically significant higher rate of leukemia than both of two control groups. The leukemia mortality rate was 5.06 times higher than the general U. S. white male population standardized for age and time period of the cohort exposure, and 4.74 times higher than a cohort of 1447 white males employed at an Ohio fibrous-glass construction products factory. These results were based on a 75% follow-up of the vital status of the workers. A total of 160 deaths were observed and of these there were 7 leukemia deaths four of which were

acute lyelogenous, one chronic myelogenous, and two monocytic leukemia. The worker exposure information is discussed in IV B below.

[5] IV. *Analysis of Myelogenous and Monocytic Leukemia Risks due to Benzene Exposures*

A. *General Approach*

As was noted in the benzene health document (Goldstein, et al. 1977), very little information exists that can be utilized to obtain a dose response relationship between benzene and leukemia in humans or animals.

However, if a number of simplifing assumptions are made, it is possible to construct a crude dose response model whose parameters can be estimated using vital statistics, the Infante study, historical benzene workplace standards, and a recent environmental benzene exposure study. (Mara and Lee, 1977)

We assume that for low exposures the lifetime probability of death from leukemia may be represented by the linear equation

$$P = \alpha \div \beta x$$

where α is the rate in the absence of benzene exposure and x is the average lifetime exposure to atmospheric benzene expressed in ppm. The term β is the change in the leukemia rate for each increase of one ppm of benzene in the air.

From the Infante, et al. study the relative risk of leukemia for benzene workers compared to the general population was obtained. We will denote this ratio as R and make the assumption that

$$R = \frac{R_2}{R_1} = \frac{\alpha + \beta(x_1 + x_2)}{\alpha + \beta x_1}$$

where x_1 is the exposure of the general population to benzene and x_2 is the industrial exposure to benzene.

[6] From our two assumptions we have the two linear equations in two unknowns of the form

$$RR_1 = \alpha \div \beta x_1 + \beta x_2$$

$$R_1 = \alpha \div \beta x_1$$

so that

$$\beta = R_1(R\text{-}1)/x_2$$

and βx_1 is the average lifetime risk due to ambient benzene exposures.

To utilize this technique to predict risk it is necessary to obtain estimates of R_1, R, X_1, and X_2. The estimation of each of these quantities is discussed in a separate section.

B. *Estimation of Relative Risk R*

Infante, et al. (1977) established as a lower bound a total of seven acute myelogenous or monocytic cases of leukemia in their studied cohort of 748 members. They calculated an expected value of 1.3831 cases for all forms of leukemia. From the 1971 U. S. Vital Statistics (U. S. DHEW, 1971) we note that of 7,564 cases of leukemia in white males, a total of 3,260 or 43% were myelogenous or monocytic. Thus an estimate of the relative risk for acute myelogenous and monocytic leukemia in white males is

$$R = \frac{7}{1.3831 \times 0.43} = 11.77$$

[7] C. ESTIMATION OF BACKGROUND LEUKEMIA RATE R_1

The lifetime risk to a disease can be estimated from age-specific deaths rates in the following manner. We assume that during different segments of a lifespan the total and disease specific death rates are constant. we define the following terms:

αj = death rate due to a specific disease during the j^{th} lifetime segment.

$\alpha j \div \lambda j$ = total death rate during j^{th} lifetime segment.

S_j length of j^{th} lifetime segment.

$P_{1j} = \frac{\alpha j}{\alpha j \div \lambda j}$ = probability of death due to the specific diseaes given that death occurred during the j^{th} lifetime segment.

$P_{2j} = 1\text{-}e\text{-}(\alpha j \div \lambda j) S_j$ = probability of death during the j^{th} lifetime segment given survival up to the start of the j^{th} lifetime segment.

$P_{3j} = \pi_{k=1}^{j} (1-P_{2k})$ = probability of survival until the start of the j^{th} lifetime segment.

If we assume that the entire lifetime is divided into m mutually exclusive segments then by definition $P_{31}=1$, $P_{2m}=1$ and the entire lifetime probability of the disease is

$$P = \sum_{j=1}^{m} P_{1j} P_{2j} P_{3j}$$

[8] The age specific rates for white males for myelogenous and monocytic leukemia were estimated from the total leukemia rates by multiplying the entries in Table I-13, disease categories 204-207, white male (U. S. DHEW, 1971) by 0.43. This gives the entries j shown in Table 1. The total mortality $\alpha j + \lambda j$ is also obtained from table I-13 and is shown in Table 1. The other terms are calculated by the given definitions and the final result, the lifetime risk of white males exposed to background levels of benzene is found to be

$$R_1 = 0.38987 \times 10^{-2}$$

[9]

TABLE 1

COMPUTATION OF LIFETIME RISK OF MYELOGENOUS-MONOCYTIC LEUKEMIA

Age Intervals	Sj	αj	$\alpha j + \lambda j$	P_1	P_2	P_3	$P_1P_2P_3$
1	1	.73	1,852.8	$.3940 \times 10^{-3}$	$.1836 \times 10^{-1}$	1.	.0000072
1-4	4	1.68	79.6	$.2111 \times 10^{-1}$	$.3179 \times 10^{-1}$	.9816	.0000659
5-14	10	1.38	40.5	$.3407 \times 10^{-1}$	$.4042 \times 10^{-1}$	.9785	.0001348
15-24	10	.95	127.6	$.7445 \times 10^{-2}$	$.1268 \times 10^{-1}$	.9745	.0000920
25-34	10	1.03	155.4	$.6628 \times 10^{-2}$	$.1542 \times 10^{-1}$	.9621	.0000983
35-44	10	1.38	309.6	$.4457 \times 10^{-2}$	$.3049 \times 10^{-1}$	.9473	.0001287
45-54	10	2.58	708.7	$.3640 \times 10^{-2}$	$.6842 \times 10^{-1}$	.9184	.0002287
55-64	10	6.41	1,632.0	$.3928 \times 10^{-2}$	.15058	.8556	.0005061
65-74	10	15.57	3,586.1	$.4342 \times 10^{-2}$	.30135	.7268	.0009510
74-85	10	31.43	7,747.6	$.4057 \times 10^{-2}$	.53919	.5078	.0011108
85+		43.65	17,758.1	$.2458 \times 10^{-2}$	1.	.2340	.0005752
							.0038987

$R_1 = 0.0038987$

[10] D. ESTIMATE OF AVERAGE AMBIENT BENZENE EXPOSURE

In a recent EPA contractor report (Mara and Lee, 1977), data relating to benzene exposure in the United States was compiled. For each of several annual average concentration ranges, the population exposed to seven categories of benzene emissions was calculated. The seven categories were: (1) chemical manufacturing, (2) coke ovens, (3) gasoline service stations (separately for people using self-service stations and for people living in the vicinity of the stations), (4) petroleum refineries, (5) solvent operations, (6) storage and distribution of benzene and (7) urban exposures related to automobile tailpipe and gasoline tank emissions. The general procedure used was to start with production data for benzene or its major products, estimate emission factors (benzene release per kg of end product), apply an appropriate air dispersion model to obtain concentrations as a function of distance from the source, and to use population density information for each location to calculate the number of people exposed to each concentration range. Air monitoring data were used whenever it was available. The results are summarized in Table 2. From this data one can calculate that the annual average exposure of an individual to ambient benzene from all sources is 1.03 ppb.

[11]

TABLE 2.

SUMMARY OF POPULATIONS EXPOSED (THOUSANDS) TO ATMOSPHERIC BENZENE EMISSIONS[a]

Concentrations (ppb)	Total Population	Chem. Mfg.	Coke Ovens	Gasoline Stations		Petroleum Refineries	Solvent Operations	Urban Exposures
				Self Service	Vicinity			
0.042	37,000			37,000				
0.50	185,297	7,497	15,726		87,000	6,529	208	68,337
								45,353
1.50	77,913	970	521		31,000	64	5	
3.00	509	453	50			4	2	
7.0	646	644	2					
30.0	319	319						
	301,684							
Population Weighted Averages (ppb)	0.7514	2.0885	0.5404	0.042	0.7627	0.5112	0.5465	0.8989

Average exposure to the population of 220 million is $\frac{0.7514 \times 301{,}684 = 1.030 \text{ ppb}}{220{,}000}$

[a] Adapted from Mara and Lee (1977).

[12] E. ESTIMATION OF AVERAGE OCCUPATIONAL EXPOSURE

Information about the plant benzene levels is contained in the Appendix to the testimony of Baier at the OSHA benzene hearings (Baier, 1977).

From the opening of the factory in 1940 until 1946, no monitoring records were available. Following the installation of new ventilation equipment in 1946, a survey showed that "most areas" in the plant ranged from 0 to 15 ppm and that all areas were less than the maximum safe limit of 100 ppm which prevailed at that time. From this information, one can guess that the average exposure to all people in the plant before 1946 is probably not much more than 100 ppm, and not less than 15 ppm.

Benzene levels were monitored after 1946 at various plant locations but they were all instantaneous samples and no reliable information is available about how many man-hours were spent at those locations or whether protective masks were worn. These are case reports of exposures of 1000 ppm for short time intervals. Since the average levels were generally close to the occupational standard, we will make the assumption that the average worker exposure was the same as the prevailing recommended occupational limits. These are tabulated below along with the time weighted average for the 36 years of the total exposure period.

Time Interval	Average Exposure(ppm)	Time-Weighted Average(ppm)
1940-46 (7)	100-15	
1947 (1)	50	39.9-23.3
1948-56 (9)	35	
1957-68 (12)	25	
1969-1975(7)	10	

[13] The actual levels to which the workers were exposed was a subject of heated debate at the OSHA benzene hearings. The CAG would like to see a realistic estimate of the population weighted average exposure and its uncertainty limits. The time-weighted averages for occupational exposure must be converted to a continuous exposure life-time basis. It will be assumed that the

maximum likely lifetime exposure would result if a worker entered the factory in 1940 and was exposed to 82 ppm for 10 years and 23.7 ppm for 25 years (which is equivalent to an average of 40.36 ppm for 35 years) and the least likely exposure would occur if a worker started in 1950 and was exposed to 23.7 ppm for 25 years. Therefore the equivalent continuous lifetime exposures are:

$$\text{High estimate: } 40.36 \times \frac{240}{365} \times \frac{1}{3} \times \frac{35}{70} = 4.4 \text{ ppm}$$

$$\text{Low estimate: } 23.7 \times \frac{240}{365} \times \frac{1}{3} \times \frac{25}{70} = 1.8 \text{ ppm}$$

[14] F. CONCLUSIONS

Given the following derived estimates of our parameters of interest:

$$R = 11.77$$

$$R_1 = 0.38987 \times 10^{-2}$$

$$X_1 = 1.030 \times 10^{-3} \text{ ppm}$$

$$X_2 = 1.8 \text{ to } 4.4 \text{ ppm}$$

the parameter β and the resulting lifetime risks and expected number of acute myelogenous and monocytic leukemia deaths can be derived in the manner previously indicated. In table 3 the average risk rates and expected number of cases per lifetime and per year are shown for total benzene exposure. In Table 4 the total rates and cases are subdivided by source of exposure. We note that about 85% of the total number of cases are directly related to the use of gasoline.

It should be emphasized that due to the very crude methods that were necessarily employed in the estimation of benzene exposures by both CAG for Infante's cohort and Mara and Lee (1977) for the U.S. population, the estimates could easily be in error by several orders of magnitude. This is true even if the form of the mathematical response model used is a correct rescription of benzene induced leukemia, which is also open to question.

However, an additional independent negative study of workers exposed to benzene (Ott, et al. 1977, Dow Chemi-

cal Company) can be used to ascertain whether our model, based on Infante's data, grossly over-estimates the leukemia risk to benzene exposure. They reported the mortality [15] experience of a cohort of workers whose exposure to benzene had been carefully documented since 1940. No excess of leukemia was observed in the cohort by 1973. Since the prediction model was previously discussed based upon workers with highly uncertain exposures, it was felt to be important to estimate the number of leukemia cases we might expect in Dow's cohort if our model was valid.

Using Dow's exposure estimates and expected number of cases for its workers, it was found that our model predicted from 1.43 to 1.74 cases of leukemia where one case was actually observed. Since this estimate is well within the limits of normal statistical variability we can be confident in claiming that the Dow study does not offer any evidence upon which to question the validity of our model.

[16]

TABLE 3

TOTAL U.S. POPULATION RISKS TO BENZENE

Industrial Exposure (X_2)	$\beta = .4149 \times 10^{-1}/X_2$	Average Risk βX_1	Lifetime Exp. Leukemia Cases in U.S.	Expected Number of Cases/Year
High = 4.4 ppm	$.9609 \times 10^{-2}$	$.9897 \times 10^{-5}$	2,177	31.1
Low = 1.8 ppm	$.2399 \times 10^{-1}$	$.2471 \times 10^{-4}$	5,436	77.7*

* This represents about 1.2% of cases observed in 1971.

[17]

TABLE 4.

RISK AND LIFETIME EXPECTED NUMBER OF LEUKEMIA CASES DUE TO BENZENE EXPOSURE FOR DIFFERENT SOURCES

Source of Exposure	Average Level of Exposure ppb.	Population Exposed Millions	Risk Rates $X_2=4.4$	Risk Rates $X_2=1.8$	Lifetime Expected of Leukemia Cases $X_2=4.4$	Lifetime Expected of Leukemia Cases $X_2=1.8$
Chem. Mfg.	2.0885	9.98	$2.x10^{-5}$	$5.00x10^{-5}$	200	499
Coke Ovens	.5404	16.30	$5.19x10^{-6}$	$1.30x10^{-5}$	85	211
Self-Ser. Gas Stations	.042	37.00	$4.04x10^{-7}$	$1.01x10^{-6}$	15	37
Vicinity of Gas Stations	.7627	118.00	$7.33x10^{-6}$	$1.83x10^{-5}$	865	2,162
Petroleum Refineries	.5112	6.60	$4.91x10^{-6}$	$1.23x10^{-5}$	32	81
Solvent Operations	.5465	.22	$5.41x10^{-6}$	$1.35x10^{-5}$	1.2	3
Urban Exposures	.8989	113.69	$8.64x10^{-6}$	$2.16x10^{-5}$	982	2,456
Total	1.030	220.00*			**2,180	**5,449

* Does not sum due to multiple exposure.

** This represents about 1% of the number of cases expected in a lifetime assuming current incidence rates.

[18] REFERENCES

1. Baier, E. J. "Statement of the National Institutes of Occupational Safety and Health", Exhibit 64A, OSHA Benzene Hearings, July 19-Aug. 10, 1977.
2. Goldstein, B. D., C. A. Snyder, R. Snyder, R. and S. R. Wolman, "Review of Benzene Toxicity," prepared for EPA, August 18, 1977.
3. Infante, P. F., J. K. Wagoner, R. A. Rinsky, R. J. Young, "Leukemia in Benzene Workers," Lancet, p. 76-78, July 9, 1977.
4. Mara, S. J. and Lee, S.S., "Human Exposures to Atmospheric Benzene" EPA contract 68-01-4314 with Stanford Research Institute, September, 1977.
5. Ott, M. G., J. C. Townsend, W. A. Fishbeck, R. A. Langner, "Mortality Among Individuals Occupationally Exposed to Benzene" Exhibit 154, OSHA Benzene Hearings, July 19-August 10, 1977.
6. U. S. Department of Health, Education and Welfare. "Vital Statistics of the United States, 1971, Volume II-Mortality, Part A", Superintendent of Documents, U.S. Government Printing Office, Stock No. 017-022-00378-3.

   Warren, E. W., R. F. Van Voorhee, A. F. Sampson, "Post Hearing Brief of API, NPPA, and Individual Member Companies Regarding the Proposed Revised Permanent Standards for Occupational Exposure to Benzene", OSHA Docket No. H-059 September 22, 1977.

   Young, R. J. National Institute of Occupational Safety and Health, Personal Communication, October, 1977.

[The following document was attached to the reply brief of the American Petroleum Institute in the Court of Appeals]

AFFIDAVIT OF DR. STEVEN H. LAMM

I, Dr. Steven H. Lamm, being duly sworn, do state and depose as follows:

1. I was graduated from the University of Southern California in 1968 with the degree of Doctor of Medicine. From 1968 to 1969, I held a rotating internship at the University of Oregon. From 1969 to 1970, I held a residency in pediatrics at the Montreal Children's Hospital. From 1970 to 1972, I was employed by the United States Public Health Service as an epidemiologist attached to the Connecticut State Department of Health. From 1972 to 1973, I was Senior Pediatric Resident at the Bronx Memorial Hospital, Albert Einstein School of Medicine. From 1973 to 1974, I attended the London School of Hygiene and Tropical Medicine, in London, England. From 1974 to 1976, I was Senior Epidemiologist at the National Institute of Child Health and Human Development of the National Institutes of Health. From 1976 to 1977, I was in private practice as a pediatrician and as a consultant in epidemiology. From 1977 to the present time, I have been an associate with Tabershaw Occupational Medicine Associates.

2. I appeared as a witness for the Manufacturing Chemists Association during the hearing held last summer by the Occupational Safety and Health Administration (OSHA) on the proposed standard for occupational exposure to benzene. In the course of preparing my testimony and attending the hearing, I became thoroughly familiar with the evidence associating occupational exposure to benzene with leukemia, particularly the study conducted by Infante, *et al.*[1]

3. In December of 1977, I prepared and presented to the Environmental Protection Agency's Science Advisory Board a review and critique of the preliminary report by EPA's Carcinogen Assessment Group (CAG) entitled "Population Risk to Ambient Benzene Exposures."[2] I have the following comments on the CAG report as it compares to the risk estimate developed by Dr. Richard Wilson, presented to OSHA during the 1977 benzene hearing.[3] I have reviewed and am thoroughly familiar with both documents.

4. In its brief filed in the above-captioned case on June 8, 1978, OSHA cites the CAG's preliminary findings of 30-80 cases of leukemia from exposure to ambient levels of benzene as discrediting Dr. Wilson's analysis, which concluded that OSHA's 1 ppm standard will prevent, at most, 2 cases of cancer every six years.[4] OSHA's use of the CAG estimates, which are based on the lifetime continuous exposure of a population of 220 million people, is specious and seriously misleading as applied in the occupational context. I have performed a series of calculations (See Exhibit A) which show that the CAG's risk estimate, when translated to the occupational context, is fully consistent with—indeed, somewhat lower than—Dr. Wilson's estimate.

5. The CAG and Wilson estimates are based on risk estimates of two *different* populations with two *different* sets of exposure assumptions. The CAG estimate of 30-80 cases is an estimate of the number of cases of acute non-lymphocytic leukemia deaths that might occur annually if the USA total population of 220 million people were exposed continually throughout their lifetime, 24 hours a day, 365 day a year, to a benzene concentration of one part per billion in air.

6. The Wilson estimate of one leukemia case and one additional cancer case in 6 years is based on the assumption that for a year 30,000 workers exposed to benzene at a level between 1-10 ppm are exposed 8 hours, 240 working days a year at an average level of 3 parts per

[1] Infante, Rinsky, Wagoner & Young, *Leukemia Among Workers Exposed to Benzene* (April 28, 1977) (OSHA Exhibit 40).

[2] The CAG Preliminary Report is attached as Addendum C to OSHA's brief filed on June 8, 1978 in the above-captioned case.

[3] Testimony of Dr. Richard Wilson, Ex. 149.B.

[4] OSHA Brief 87 n.80.

million benzene in the air. The figure of 30,000 is obtained from page 1-7 of the Economic Impact Study of the proposed standard prepared by OSHA by Arthur D. Little, Inc.

7. In order to compare these estimates, they must be related to the same exposure level and time and to the same population. CAG indicates that their case numbers are based on an estimation that the lifetime (70 year) risk of leukemia due to lifetime (70 years), continuous (24 hours/day, 365 days/year) exposure to 1 ppb benzene in air is from 1 x 10^{-5} to 2.5 x 10^{-5}.[5] Wilson's case numbers derive from the assumption that 1.8 x 10^{-6} is the yearly risk of a worker dying from leukemia from having been exposed for one work year of 8 hours/day, 240 days/year to a level of 1 part per million benzene. Attached Exhibit A reviews the algebra necessary to compare the two estimates.

8. Assuming an average lifetime of years, Equation 2 divides the CAG risk by 70 and identifies the lifetime risk for *1 year*, continuous exposure to 1 ppb of benzene as [from 0.14 to 0.36] x 10^{-6}, or [from 140 to 360] x 10^{-9}. In Equation 3, I again divide by 70 to produce the *annual* risk of 1 year, continuous exposure to 1 ppb of benzene, which is [from 2.0 to 5.1] x 10^{-9}.

9. Workers do not work 24 hours a day, which is the exposure period assumed in the CAG model, but generally work only one-third of a day (8 hours). Therefore, Equation 4 divides the CAG risk by 3, to produce a risk of [from 0.7 to 1.7] x 10^{-9}, as the annual risk for 1 year of eight-hour daily exposure to 1 ppb of benzene.

10. In addition, the CAG estimate assumes exposure every day of the year, but workers do not work every day. Therefore, weekends, holidays and vacations, amounting to about one-third of the full year, must be excluded. Equation 5 accomplishes this, and shows an annual risk for 1 *work*-year of eight-hour workday exposure to 1 ppb [from 0.45 to 1.1] x 10^{-9}.

11. Finally, the CAG assumes exposure to 1 part per *billion* of benzene. To obtain the risk of exposure to 1

[5] CAG Preliminary Report, Table 3.

part per *million* of benzene, the risk must be multiplied by a factor of 1000, and Equation 6 reveals that, based on the CAG's risk estimate, the annual risk of 1 work year of eight-hour workday exposures to 1 part per million of benzene is [from 0.45 to 1.1] x 10^{-6}.

12. Thus it is shown that CAG's estimate of lifetime risk of acute non-lymphocytic leukemia (ANLL) death of [1.0 to 2.5] x 10^{-5} for lifetime continuous environmental exposure to 1 ppb benzene is equivalent to a [0.45-1.1] x 10^{-6} annual risk of ANLL death for 1 year of occupational exposure (8 hours/day, 240 days/year) to 1 ppm benzene.

13. Dr. Wilson has based his case count on an annual risk of death from *all* types of leukemia (not just ANLL) of 1.8 x 10^{-6} for one work year of occupational exposure to 1 ppm benzene. Since only 43% of leukemia deaths are due to acute nonlymphocytic leukemia, the Wilson risk can be translated into a 0.77 x 10^{-6} risk of acute nonlymphocytic leukemia death from one work year of occupational exposure to 1 ppm benzene.

14. Thus, Wilson and CAG have reached the same estimate of the annual risk of acute non-lymphocytic leukemia death due to one work year of occupational exposure to 1 ppm benzene, to wit,

CAG estimate = [from 0.45 to 1.1] x 10^{-6}
Wilson estimate = 0.77 x 10^{-6}

15. Based on the data provided in the Arthur D. Little Study, Dr. Wilson assumed that the 30,000 workers exposed to between 1 and 10 ppm are exposed to an average of 3 ppm benzene. It therefore follows, using the CAG estimate, that a reduction in these workers' exposure to benzene from 3 ppm to 1 ppm might reduce their ANLL mortality annually for each year of exposure by

(0.45 to 1.1 x 10^{-6}) x (1 work year) x (3 ppm-1 ppm) x (30,000 people) = ([0.45 to 1.1] x 10^{-6}) x 1 x 2 x 30,000 = (.027-.066) cases ANLL/year.
= one case every 15-37½ years

Use of the Wilson estimate of .77 x 10^{-6} would predict .046 excess cases ANLL each year or 1 case every 21 years.

16. Wilson's estimate of one leukemia case and one other cancer case in 6 years was based on three additional conservative assumptions.

a. *All* leukemias (not just ANLL) are benzene related.

b. For every benzene leukemia there would be another cancer at another site in the body due to benzene exposure.

c. Benzene exposure of those currently exposed to 1 to 10 ppm benzene would be far less than 1 ppm if a new standard were introduced.

There is no reason to believe the need for any of these pessimistic assumptions, but these assumptions account for the different numbers derived from the Wilson risk estimate.

17. It is concluded, based on the CAG estimate and its underlying assumptions, that reduction of occupational benzene exposure from 10 ppm to 1 ppm for each year of work might reduce the annual mortality for acute non-lymphocytic leukemia by 1 case every 15-38 years.

18. The CAG estimated range was based on the premise that the Infante cohort was exposed to a mean occupational exposure of 24-40 ppm benzene. This was based on the assumption that the exposure was at the maximum permissible exposure level in effect from time of hire in the forties to the end of study period 1975. This assumption leads to an under-estimation of the levels of exposure because: 1) industrial hygiene data show that nearly half the surveys indicated levels greater than the TLV at that time; and 2) the inclusion of exposure estimates through 1975 is inappropriate since all the leukemia deaths occurred prior to 1962 and the period of exposure necessary to inclusion in the study ended in 1949; and 3) the estimate ignores exposures prior to 1941 when no maximum exposure standard existed and during which many employees worked. Evidence in the hearing indicated that levels of exposure exceeded 100 ppm in the forties.[6] If the CAG estimates was recalculated under the assumption that the exposure was at 100 ppm (rather than 24 or 40 ppm), the risk estimate would be further reduced by 60% to a risk estimate of about 0.20 x 10^{-6}, which would predict that OSHA's 1 ppm standard would avoid .012 cases ANLL per year, or about one case in 83 years.

[6] See Brief of API, AISI, MCA and IPAA, the printed version of which was filed in the above-captioned case on June 13, 1978, at pp. 15-18, 36-37.

19. The purpose of this exercise has been to indicate the similarity between the risk estimates produced by CAG and by Dr. Wilson. My purpose has not been to prepare a new, independent estimate of the effect of OSHA's standard. As indicated by CAG's acknowledgement that its risk estimate may be off by several orders of magnitude, risk estimates are necessarily imprecise because of the large number of variables (such as exposure levels, non-occupational exposures, etc.) for which accurate information is not available. Nonetheless, it is encouraging that the two different attempts to conservatively address these issues compared here have reached results so similar.

STEVEN H. LAMM

EXHIBIT A

(1) $[1.0 \text{ to } 2.5] \times 10^{-5}$ = $[10 \text{ to } 25] \times 10^{-6}$

= CAG estimate of lifetime risk of lifetime, continuous exposure to 1 ppb of benzene

(2) $\frac{[10 \text{ to } 25] \times 10^{-6}}{70}$ = $[0.14 \text{ to } 0.36] \times 10^{-6}$

= $140 \text{ to } 360 \times 10^{-9}$

= lifetime risk for 1 year, continuous (24 hour) exposure to 1 ppb

(3) $\frac{[140 \text{ to } 360] \times 10^{-9}}{70}$ = $[2.0 \text{ to } 5.1] \times 10^{-9}$

= *annual* risk for 1 year, continuous (24 hour) exposure to 1 ppb

(4) $\frac{[2.0 \text{ to } 5.1] \times 10^{-9}}{3}$ = $[0.7 \text{ to } 1.7] \times 10^{-9}$

= annual risk for 1 year, 8 hour daily exposure to 1 ppb

(5) $\frac{240}{365} \times [0.7 \text{ to } 1.7] \times 10^{-9}$ = $[0.45 \text{ to } 1.1] \times 10^{-9}$

= annual risk for 1 *work* year of 8 hour, workday exposure to 1 ppb

(6) $[0.45 \text{ to } 1.1] \times 10^{-9} \times 10^{3}$ = $[0.45 \text{ to } 1.1] \times 10^{-6}$

= annual risk for 1 work year of 8 hour workday exposure to 1 part per *million*

UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

Nos. 78-1253, 78-1257, 78-1486, 78-1676, 78-1677, 78-1707, 78-1745, 78-1988, 78-1989, 78-2642, 78-2779, and 78-3023

OSHA No. 77-1395

* * * *

Before Coleman, Clark and Tjoflat, Circuit Judges.

JUDGMENT

These causes came on to be heard on the petitions of the American Petroleum Institute, et al., and were argued by counsel;

ON CONSIDERATION WHEREOF, It is now here ordered and adjudged by this Court that the petitions for review of an order of the American Petroleum Institute, et al., in this cause be, and the same are hereby granted; the provisions of the order reducing the airborne permissable exposure limit and the dermal contact prohibition are set aside and the remaining provisions of the standard in this cause be and the same are hereby vacated.

It is further ordered that respondents pay to petitioners the costs on appeal to be taxed by the Clerk of this Court.

October 5, 1978

Issued As Mandate:

SUPREME COURT OF THE UNITED STATES

No. 78-911

INDUSTRIAL UNION DEPARTMENT, AFL-CIO, PETITIONER

v.

AMERICAN PETROLEUM INSTITUTE, ET AL.

ORDER ALLOWING CERTIORARI. Filed February 21, 1979

The petition herein for a writ of certiorari to the United States Court of Appeals for the Fifth Circuit is granted. The case is consolidated with No. 78-1036 and a total of one hour is allotted for oral argument.

SUPREME COURT OF THE UNITED STATES

No. 78-1036

RAY MARSHALL, SECRETARY OF LABOR, PETITIONER

v.

AMERICAN PETROLEUM INSTITUTE, ET AL.

ORDER ALLOWING CERTIORARI. Filed February 21, 1979

The petition herein for a writ of certiorari to the United States Court of Appeals for the Fifth Circuit is granted. The case is consolidated with No. 78-911 and a total of one hour is allotted for oral argument.

[The following testimony is from the reporter's transcript of the rulemaking hearing on the proposed benzene standard]

* * * *

[859] MR. JACOBSON: Thank you. One other question here and that is the employes that were cited here had considerable dermal exposure as well as exposure in the working atmosphere as far as inhalation. Does anyone on the panel have any feeling as to whether this dermal exposure is a contributing factor or [860] is the addressing of the dermal problems with benzene in this proposed standard for problems other than leukemia.

DR. DOUGLAS SMITH: I can start it off and then if someone wants to continue it a little bit, they can. Yes, the problem of dermal absorption is, I think, real. Benzene in relation to other aromatic materials, by comparing it let's say to toluene and xylene. Apparently it is not absorbed through the skin at the same rate as toluene and xylene but it nonetheless can be absorbed.

Even if you take and have a situation in which you have got an inflamed skin or some abnormal situation, or if you have got it contained in a mixture, I believe that a considerable amount can be absorbed. I believe that this has been demonstrated in the past with measurements of urinary phenol from dermal absorption of benzene.

We don't consider that it is absorbed as a clear compound extensively. It can be.

MR. BAIER: Maybe Blair or Bob would want to discuss it from a medical standpoint.

DR. LAIGO: Well, it can be absorbed through the skin, it is readily absorbed through the skin. To what extent it would be absorbed in any particular exposure, you don't really know. You can't measure that. It certainly is a significant thing and if people are getting it on their skin, it certainly could be significant.

* * * *

[2104] MR. WARREN: Dr. Zachauser?

DR. ZACHAUSER: I am Richard Zachauser, Professor of Political Economy at Harvard University. My

fellow witnesses have testified on the adequacy and in adequacy of the Arthur D. Little report. I will not focus on that for two reasons: [2105] First, I think that the Arthur D. Little Company, assuming that it was at all responsive to its assigned task, was given the wrong task. Second, I don't think that the findings of the Arthur D. Little study, whatever they might reasonably have been, would likely have influenced the final decisions that OSHA would make. This suggests that we are in an unfortunate position where analysis is not employed to affect decision making, but might be thought of more as a charade.

Let me discuss the way an economist looks at this problem, indeed, at any problem. The science of economics is basically devoted to a very simple problem. How should we allocate resources to competing objectives. With this problem there are two objectives: One is to have economic resources available to accomplish other purposes. The second one is to promote human health.

The economic resources that are involved here are quite substantial accepting on face value the Arthur D. Little report. We are talking about $267 million worth of capital costs, $124 million worth of first year operating costs, $76 million of continuing operating costs. At any reasonable rate of discount, this is a $1 billion decision. It would be reasonable to ask, under the circumstances, what are we accomplishing? What are we buying for our $1 billion expenditure or rather, what are the people who are being forced to spend their money buying for their $1 billion expenditure.

[2106] We have a little bit of information in the Arthur D. Little report. For example, we know that there are 30,000 who are at risk levels above one part per million. We do not know, however, what happens to these 30 thousand workers. We know they are to be moved below a standard, but we don't know whether we are getting rid of 20 cases of leukemia, 10 cases of leukemia, one case of leukemia, the expected value of .001 cases of leukemia. I think that information is obviously vital to our decision making process.

The objection might be raised that we do not want to put a price tag on human lives. OSHA has continually

maintained that there is no legitimate procedure for putting a price tag on human lives and I wouldn't disagree with that. I would say that we want full information so that people in authority in the decision making process will be able to see what trade off they are making.

Basically to adopt the notion that we don't have to quantify the health benefits. Not just saying that there are health benefits, however small. There was testimony earlier that they might be non existent. To say what the actual health benefits are, I think, is essential and to argue the contrary is to say that ignorance is better than knowledge. I think that is not a very sensible thing to do.

Is there anything that we can do where we don't want to put a price tag on human lives? I think the answer is [2107] yes we can try to follow what economists refer to as a cost-effectiveness approach. Basically, for whatever resource dollars we are going to spend for promoting health, we try to achieve the maximum level of benefits. In order to do this, you have to know what benefits are going to come out of that type of expenditure.

All the time we are incurring risks because we think we get other benefits. We let people drive cars even though we know that if we put the speed limit down 20 miles per hour, we would have fewer accidents. At zero miles per hour, we would have no accidents. We allow people to eat rich desserts, live in wooden houses instead of brick houses which would be safer and I would say in all of these areas the level of risk, even if you make the most exagerated estimate of the leukemic affect of the exposure to benzene and other health consequences are much greater than the ones we are confronting here today.

I say also that the government in its regulatory processes is getting into this problem in a very major way. I was reading the Washington Post this morning and there was an article on what is called CAT scanners, computer assisted tomography which is a sophisticated diagnostic technique that assists in various medical procedures. The Federal government is presently getting into the position of regulating the use of these scanners

not that it doesn't help in an occasional instance to diagnose a very difficult disease, but the benefits in terms of improved diagnosis and medical treatment aren't worth the cost.

[2108] Here we know what the costs are, or at least we know one estimate of costs. We have no notion of what the benefits are. I should say, by the way, that other areas of government have followed the approach of putting a price tag on human lives. For example, the National Highway Traffic Safety Administration which is responsible for such things as tire standards or air bags, uses a figure of $250,000 per life safed.. I would say that if you figure the $1 billion cost per 30,000 workers, that is $30,000 per worker. That would mean that if we are being consistent with NHTSA, we would have to save one out of every eight workers.

I don't think that anybody would argue that one out of every eight workers who is presently above the one part per million standard is going to suffer from leukemia, much less die of it.

Consumers Union, which is a consumer oriented protection group, uses a figure of $1 million. Various other studies have cited numbers ranging from $150,000 to perhaps $3 million. I think it is critical that we recognize that trade off's are being made here and that we have to at least have the information as to what types of benefits one part per million offers us.

Let me get to my point about it not mattering what Arthur D. Little found. Let's assume that all the costs of the Arthur D. Little study were multiplied by three. This becomes a $3 billion rather than a $1 billion expenditure. Would any de- [2109] cision, would any of the evidence presented today, vary in any way. Take another hypothetical. Let us assume that the previous witnesses had been able to quantify exactly how many lives would have been saved. Then they corrected their testimony and they said no, we are off by a factor of 10. Only one tenth as many people would be affected as we originally said. Is there anything that is part of this decision making procedure that would reflect that change in evidence?

I think that the answer is no. Unfortunately we haven't acquired the evidence so that we could even test that particular hypothesis. I would like to make one further point about how one should treat costs here. All of the costs in the Arthur D. Little report and indeed in virtually all of the OSHA standards that I have read about, deal with average costs. They say how much will it cost us to move from ten parts per million to one part per million.

They don't ask the question about the benefits, but what we should like to know is not only how much does it cost us to move from 10 to one but how much does it cost us to move from 10 to two. We could always set the standard at two parts per million. We don't have to deal with rounder numbers. Then we could see whether the further reduction to one part per million was worthwhile.

For example, if 20 cases of leukemia per year would be saved by this particular standard, then the cost of saving one [2110] life would be $50 million. Let's assume, though, that we could save 19 of those cases for half of the expenditures by moving to two parts per million. Then that last life is costing us ten times as much. I think that the point that should be recognized is that when ADL or OSHA, when ADL conducts a study or when OSHA formulates and promulgates a standard, some attention should be marginal benefits and costs to further reductions seems absolutely essential.

I would like to pose one disagreement I did have with OSHA in general and its treatment of economic costs which is that generally they only count when they get above a threshold. This is surprising for an agency that doesn't accept thresholds going in the opposite direction to say that only if something is above five percent or only if an industry is closed down, in which case the real resources spent are, as Professor Henderson and Dr. Scarbrough testified, are underestimated. Should we count this as economic costs that conceivably should affect our decision?

So let me summarize very briefly what I say in my testimony. First, the proposed permanent standard: It

is not clear that any principal was used to set the standard. One part per million is just as good as two parts per million or three parts per million. There is an available technology methodology widely accepted in economics, widely accepted in the health care area, which is cost-effectiveness where we attempt to achieve [2111] maximum benefits per dollar expenditure.

Second, no attempt was made to determine marginal benefits. What will you gain if you tighten or lossen control? Third, no attempt was made to measure benefits. We get the same conclusion that I suggested earlier. Do we have much greater benefits or much lower benefits? Within the standard itself, there is little attempt to direct resources to where they would do the most good. It is noteworthy that this standard, one-third of the operating costs during the first year are directed to medical survailance, one third are directed to monitoring of conditions and one third are directed to reducing the risks.

Well, do we have the appropriate information as to what gains we get out of either one of these different areas? If we did, then we could use even $1 million worth of resources to achieve substantially more health benefits both within the benzene related industries and in other industries.

I guess what I would recommend for action is to understand that we do not have the appropriate information that would enable OSHA to adopt, to reject, or to modify its standards. What is needed now are analyses to compute the total benefits from various levels of standards and also information which was not provided on marginal benefits and costs.

Unless we have this information, any decision taken by OSHA now must reflect an emotional or political response to an uncharted situation where the information isn't available. [2112] I would hope that intelligent and well informed decision making should be given a chance. Thank you.

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[2141] MR. LE SOURD:

Let me turn to Dr. Zeckhauser's testimony if I may. Do I understand, Dr. Zeckhauser, that you are advocat-

ing the use of the techniques of the discipline called policy analysis and specifically that the application of cost effectiveness analysis in the formulation of occupational health standards? I am correct?

DR. ZECKHAUSER: I would say it is more than policy analysis. It is basically the way most effective government decisions are made and are sometimes put under that head. It is part of economics. It is part of government decision making.

MR. LE SOURD: You are recommending cost effectiveness?

DR. ZECKHAUSER: Yes, I am.

MR. LE SOURD: Yes. Further, are you recommending that no action be taken to promulgate such a standard as this proposal?

DR. ZECKHAUSER: I wouldn't make that recommendation. The reason being all that I have learned from reading the Arthur D. Little report and I have not reviewed the medical evidence. I have heard a little bit of it. I have discussed it with people at API and with their legal counsel. All we know is the cost of [2142] this information. It is $1 billion. We know nothing about the benefits of this information. That strikes me as making a decision in ignorance. I think we should get some notion of what the effectiveness will be before we decide to make a decision of this sort. So my answer would be yes. We have no basis to make any possible decision.

However, there are some improvements we could make even if we had to make a decision. I tried to be cost effective within the standard. Looked to see which expenditures seemed most wasteful. But I would prefer to get the basic information as to what level of protection, if any, would be afforded.

MR. LE SOURD: Is cost effectiveness always of the applicable principal for use in regulatory action of this sort?

DR. ZECKHAUSER: In protective regulation, it is frequently very useful. There are some times where a government regulatory agency may feel that it can put a price on a level of protection that is afforded. Otherwise it might chose to value a life.

I generally don't think that that is very helpful. OSHA has objected violently to it and has therefore stopped its analysis more or less burrying its head in the sand.

Cost effectiveness analysis just gives you a way of utilizing information to see, for example, that here maybe we are saving a life at a cost of $50 million where as we are failing to save lives, for example with the CAT scanner that I [2143] mentioned earlier, that would cost $500,000. We put more of our resources into CAT scanners which has been identified as a rather wasteful technology by the government and less into protecting workers in this way possibly offering very minimal benefit, then we would be using cost effective analysis to do that determination. The basic principal is that it highlights the trade off's and allows decision makers at all levels. As you know, the President of the United States has expressed an interest in OSHA's decision making processes to learn what is being gained at what cost.

This is precisely the information, for example, that the workers in the refineries themeselves and the other establishments would use if they owned the refinery and had to make the decision, should we protect ourselves? My guess that if they did attempt to make that decision, they might decide that it was worthwhile living with a little more protective equipment. As you know, that is a very cost effective way of protecting people, but as you know that is also ruled out by traditional OSHA procedures.

I think that quantifying the effectiveness and the costs of various types of impositions would immediately inform decision makers within OSHA, within the government and within the nation as a whole as to what is being gained at what cost and would enable OSHA to rationalize its interventions getting more occupational safety and health for whatever level of re- [2144] sources that are spent.

* * * *

[2149] MR. LESOURD: Dr. Zeckhauser, you have said that the guiding principle of cost effective analysis is that for whatever level of resource expenditure we are undertaking we should attempt the maximum possible

level of effectiveness. Is this a correct definition, then, of cost effectiveness analysis?

DR. ZECKHAUSER: That is part of it. The other part of it is that ultimately the decision maker should look at cost and effectiveness and decide what level of resources we want to spend. But, yes, that is an important component, and we want to get maximum effectiveness for whatever level of resources we expend.

MR. LESOURD: Would you agree that it is OSHA's obligation to provide insofar as can be accomplished a safe and healthful workplace for workers?

DR. ZECKHAUSER: As I remember the original enabling legislation, it was insofar as possible. Also, in the original legislation there was the term feasible, which has generally been interpreted to include technologically feasible. I think that any decision maker concerned for the total resources of our nation—and this is the lesson of economics that you shouldn't forget anything when you make your decision— [2150] would want to interpret that as being economically feasible as well. We shouldn't buy miniscule protection for an extra-ordinarily high amount. The problem with saying safe and healthful is how safe is safe? At what level? Why one part per million? Why not .001 parts per million Why not zero parts per million and put the petroleum industry maybe out of business if we got an absolute zero because there is no way you can assure nothing will creep through any mode of protection?

So the problem with saying safe and healthful by itself, without qualification, is that there is no level that is safe and healthful. OSHA has run into this problem with regard to a number of its standards in that they haven't been able to define that level. We had a standard of ten parts per million. If that was safe and healthful, then it is still safe and healthful. It is not as though the biology has changed at all. That was a decision we chose to make at that time on the basis of not very good information. We now it seems do not have much more good information, and we are just changing our standard.

I would like to have the information available so we could provide insofar as seems feasible and desirable a safe and healthful workplace, not meaning eliminating all risks or we would close down all of American industry.

MR. LESOURD: Did I understand then that you are [2151] equating cost effectiveness with economic feasibility? That is how you define economically feasible?

DR. ZECKHAUSER: Economic feasibility would mean that it was decided by the decision makers that the benefits were worth the cost, the marginal benefits. When we pushed it further, the marginal benefits were worth the cost. Or you may say I might refer to that as economic feasibility, yes.

MR. LESOURD: Are you saying then that in the case of this proposal for benzene that the cost effectiveness of moving from 10 ppm to 1 ppm is not sufficient to justify this change? I am not sure that I followed you.

DR. ZECKHAUSER: No, what I would say is no information has been provided so that we could compute the cost effectivenesss. We have the cost. Let us accept, subject to lowest limitations, the Arthur D. Little report as an accurate reflection of costs. Then, we would have to know—you said it yourself and you are an economist as am I—economists look at all the outputs of a process. Let us look at the costs that we are incurring. Let us look at the benefits we are receiveing. There is no discussion of the benefits. We don't know how many workers are getting protection, if any. All we know is we are moving from 10 parts per million to 1 part per million.

I would like to know how many cases of leukemia are [2152] we reducing? What other types of illness are being avoided by moving from 10 parts per million to 1 part per million? And there is no information to that effect. If we had that information, I think that a lot of this debate would go away. We are arguing in a vacuum. We know what the costs are. It is a remarkable proceeding. We know what the costs are. The argument is made that the costs aren't excessive and therefore we should have the standard. And nobody has even bothered to say, "But what are we getting for it?"

I can't say whether it is cost ineffective because nobody has bothered to tell me what the benefits are in terms of reduced healthfulness.

MR. LESOURD: Would you think that there is a difference in dealing with carcinogens versus dealing with non-carcinogenic toxic materials as to the decision that would be made?

DR. ZECKHAUSER: I think that you would want to worry about the health loss. I am as worried about workers being run over by forklift trucks as I am by workers dying of cancer. I am as worried about workers dying of heart attacks as I am by workers dying of cancer. There are losts of other diseases. Black lung disease—it bothers me tremendously. I don't like to see it, and I am delighted that we have a regulatory effort that protects miners. That is not carcinogenic.

[2153] MR. LESOURD: How difficult do you think that it would be to get an adequate dose-response function or health benefit function that would answer this question?

DR. ZECKHAUSER: I am not a doctor, but I think that the testimony earlier today, the testimony that we have been presented, put a clear upper bound on the level of benefits that could be secured. Otherwise, the debate that was going on before we came on to testify was is there any, is it equivalent to one cigarette per year, one cigarette in a life time, whatever else it might be? I think that if somebody came in and said in the most pessimistic view of the carcinogenic effects of benzene this moving from 10 parts per million to 1 part per million will save 200 lives over the next ten years and the most optimistic view of the carcinogenic effects of benzene, otherwise that it is not very carcinogenic, it will save 30 lives. Then we would know. We are saving between 30 and 200 lives, and we would say are there other ways that society can spend resources, be it air bags or mine safety or other modes of safety in the oil refinery or within the coke oven plant that will offer more health benefits for the cost?

I think we also could look for cost effectiveness even within this present standard. For example, I noticed that

there were four medical inspections per year for all sorts of different classes of workers, including some whose exposure [2154] levels were very low. That can't be cost effective. Now, it may be that we should have four for this class of workers and one per year for this class of workers unless some statistical evidence tells us that we should increase that level of surveillance. But there is no attempt to do this. It is sort of the notion of you provide absolute protection with absolute standards. As a consequence, cost effectiveness is left out of the discussion. Effectiveness is left out of the discussion. Benefits are left out of the discussion. Health is left out of the discussion except that health is at risk, and that is sufficient to set a standard.

* * * *

[2156] MR. LESOURD: You are saying then really, if I understand you, that the relative risk and probably other matters such as latency period and the dose-response function have to be known before you can make these calculations of cost effectiveness?

DR. ZEKCHAUSER: I think that we should make some [2157] effort to gather the information that we have, to collect that information before we make a decision. Yes, I would say that is the case. We can put upper bounds. The discussion this afternoon suggested that we can put upper bounds on the dose-response relationship. You may argue that it is here, and I might argue that it is here. But even if we accepted your estimate the most tangential studies we would have an upper bound of what it might be. And I think that information should be part of the standard setting process.

MR. LESOURD: On page 8 of your written testimony you stated that OSHA "should make every attempt to be consistent across the broad sweep of problems encompassed by occupational health and safety." By consistency do you mean the trade-off rates, which I believe was your term?

DR. ZECKHAUSER: Yes. If that were done, then we could be sure that the total level of impositions of OSHA we would be getting the maximum health benefits. So that if OSHA is, for example, with its cotton

dust standard, a very great health problem, sacrificing lives at $500,000, otherwise for an additional $500,000 a life could be saved, but with benzene saving a life at $50 million, then what we should do is cut our expenditures in benzene. And with that same $50 million we could save I guess—I can't remember my numbers exactly, but I think it is 1,000 workers in the cotton dust area.

[2158] MR. LESOURD: But aren't you—

DR. ZECKHAUSER: I don't remember what the numbers are—

MR. LESOURD: Isn't it true that the expenditures that the textile industry may make for compliance with the regulation are not transferrable to some other industry for them to expend. So, you are not really comparing anything.

DR. ZECKHAUSER: But to the extent that most of these expenditures are borne ultimately by consumers and taxpayers at large. The textile industry raises its prices. The benzene industry, petroleum industry, petrochemical industry raises its prices. We bear the cost particularly if demand is inelastic. So, too, if the companies lose profits half those profits are absorbed by the taxpayer at large so that an awful lot of the costs go back to, you know, John Q. Public. So, I think from that standpoint the costs are transferrable.

But I am only saying within the broad sweep. I don't mean that it has to be one to one. But let us not have it 1,000 to one. Of course, here we don't know what it is at all because we have no notion as to what that ratio is, although we can put a minimum on it.

MR. LESOURD: Then, you are not really saying that they should be equal?

DR. ZECKHAUSER: In an ideal world maybe you would [2159] have them equal. It is sufficient we are so far from the optimum that it would be good to move in the right direction. We could dramatically improve occupational health and safety, save resources at the same time, if we had a ratio where one was 100 to 1 and one was 1 to 1 by moving so that one was 30 to 1 and one was 15 to 1. As to whether they should move finally to

equality that is sort of a refinement that we can get to later.

MR. LESOURD: How far do you think that OSHA should go in comparing standards? Should it look at the total range of all possible health and safety standards and then examine the trade-off among all of these before it acts on one?

DR. ZECKHAUSER: No, I don't think it should. I think they should come up with standards as they are identified and as they come to the public view. I think if we gather the appropriate information and fed it into hearings such as this one and in its promulgation of regulations it was made available in the newspapers and to Congressmen, to the press, and the President, then very shortly there would be forces pushing towards equalization. But, I think that we should protect workers against benzene now. The question is to what level should we do that? We don't have to worry as to what we are going to be doing with cotton dust tomorrow or five years from today. But we can look to other areas. NHTSA, which I mentioned earlier, this Traffic Safety Agency, [2160] is already proposing a lot of standards that are already in effect. We can use that as a vague guideline.

We can look at OSHA's other standards as a vague guideline in terms of what we would do now. But the main thing is that if we had the information then people would comment. Congressmen would say this is outrageous. No, we didn't want to spend this amount of money. When we passed the OSHA Act, we didn't understand what was really involved. Many Congressmen are saying that.

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[2167] MR. LESOURD: Am I correct that you seem to be assuming that you know the benefits, yet you are telling us that the trouble is we don't know the benefits? Yet you are saying that the benefits of this change from 10 to 1 can't justify the costs? It seems to me that you are doing that.

DR. ZECKHAUSER: I don't think I am being clear, and I apologize. We know from earlier testimony. They were quarreling this afternoon as to what the maximum

benefits could be. We can get a maximum estimate of the benefits, and then we could say it is worthwhile. What is the most number of workers that could be protected? I think that we could provide some guess in that direction now. Maybe I am wrong. If I am wrong, that information should have been generated.

I would like to use that information to decide what we do right now. But I would also like to refine those estimates, get estimates of marginal benefits, get not the extreme valuation of the benefits but something more in the middle of the range so we can know what sensible action should [2168] be taken. So, I don't claim that we have the knowledge of the benefits.

My guess is, though, that medical witnesses would give some maximum level. I think that is what they were doing this afternoon.

MR. LESOURD: You do feel, do you, that even if all that we could ever know was what some upper bound might be on these benefits, there would still be a basis for action at some time at least when we had determined that that was all we could know?

DR. ZEKCHAUSER: Well, I don't think that we will ever determine that is all we can know. There have been many other areas where we started off with a broad guess. Eventually we refined it. I don't think that would be too hard to do. I think that it is quite possible in this case that knowing the maximum benefit might tell us what we shouldn't do. It might tell us that this present decision is wrong. It might not tell us exactly where we should set the standard, whether we should lower it as far as 5 parts per million. It might not tell us whether we should have four medical inspections per year or two medical inspections per year.

For example, in medical inspections I think we will know within one year what sort of benefits come out of four inspections per year as opposed to one inspection per year. We might run a controlled experiment. It would be very easy [2169] to do. That is not something where we have to have new insights into epidemiology. We can say, look, with these 1,000 workers we gave them four examinations per year and we didn't find anything,

with these workers we found an awful lot. You know an awful lot more about the benefits of those medical exams. I think that we could find out that information.

So, I think that the first question we should ask is, "Without our present estimates of maximum benefits and our estimates of costs, however good or bad they may be, does it seem worthwhile just to move from 10 parts per million to 1 part per million?" I think that is a question that we can ask.

And that information is not provided, and that information is not generally part of OSHA's decision making.

* * * *

[2180] DR. PARTRIDGE: Fine, given the time frame available for a variety of analyses that might be undertaken, if we were to take the approach that you are suggesting to look at a variety of potential regulations, what would we do in an interim situation where we have a potential or a known carcinogen that requires regulation?

DR. ZECKHAUSER: We would collect information on the costs. That is what your organization has done.

[2181] DR. PARTRIDGE: Correct.

DR. ZECKHAUSER: We would collect information on the benefits. There is some information that is not presented. It was not presented in your report. I take it that was not the charge to Arthur D. Little. It is normally not a charge that OSHA makes. We would provide that information, and we would make our decision on the basis of the best information that we could gather. Here we have not provided the best information that we could gather.

I would like to see in your report or in the document that promulgates OSHA standards a notion of using this piece of epidemiological evidence we estimated that these benefits would be provided, using this piece of epidemiological evidence which is much more optimistic or pessimistic or whatever else it is these would be the benefits that would be provided. This was the range that came out of the studies that we examined. That is what I would like to do. In the interim if that information were provided, I would like to compare it across

other areas. At least I would like to have it provided so that OSHA for its own internal decision making purposes would use it in a reasonable fashion.

DR. PARTRIDGE: Okay. In this type of situation then would we be able to draw upon preceding studies as a basis for future promulgation, where we are gradually [2182] accumulating a body of literature and knowledge, be it cost effectiveness or what have you.

DR. ZECKHAUSER: You certainly would, but we couldn't in the occupational health area given OSHA's refusal to quantify the benefits from its impositions. We would have to look at this time to studies done in other areas with the hope that since OSHA has been a playing an increasing strong role in the occupational health area that soon we will have broad enough studies that would be able to inform us.

DR. PARTRIDGE: Begging the issue of whether or not OSHA is willing to quantify benefits or not, would you be prepared to utilize information that is now being collected as a basis for quantifying the value of human life for a variety of regulations?

DR. ZECKHAUSER: Well, there is a difference between quantifying the benefits in terms of how many lives are saved and quantifying the value of a human life. I think that quantifying the value of a human life so turns off large groups of people that it is not something that should be done. It doesn't inform the decision making process very much, and it just gets people upset. Now I have actually seen some Arthur D. Little studies that did do that, and I think they had precisely that effect—the Pan American Health Organization worrying about the benefits of mosquito eradication.

[2188] DR. PARTRIDGE: Fine. On page 13 you make a statement more significant the uncertanties usually the greater are the benefits for some sustained study of the problem. If initial predictions of health benefits range, say, over true orders of magnitude, several months of investigation may narrow the prediction to within a factor of 10. Extremely narrowing of this sort may dramatically change both the form and severity of

the regulatory intervention that we wish to employ in a particular case.

Would you briefly describe to my what types of additional investigation you are advocating here?

DR. ZECKHAUSER: Well, what I would do is I think I suggested earlier I would start off by asking our medical witnesses to attempt to quantify the benefits, and obviously we have got a range, with some people suggesting that benzene causes more cases of leukemia than others. I think that we would be most able to narrow uncertanties in something like the frequencies of monitoring and surveillance, medical surveillance, where I think a good control study within one year could tell us an extraordinary amount, whether 50,000 exposed workers will pick up—and nobody would know right now —200 disturbing symptoms, sets of disturbing symptoms or two. You gain an awful lot knowing that, and right now if somebody were asked to testify they would have an extra-ordinarily broad range. There is a study. We could do it, [2189] do it in a year, and we would have a much better standard in a year from today.

[2190] DR. PARTRIDGE: You are talking about an almost after the fact evaluation of certain compliance activities. I prefer to go back to perhaps issues of toxicology and—

DR. ZECKHAUSER: I repeat my opinion with regard to benzene. I don't know what the level of uncertainty is over the leukogenic consequences of benzene exposure. I heard some discussion as to whether 10 parts per million was safe or one part per million was safe, and I guess we could find out something more about that. I would like to see those studies conducted. It might take some time. At the outset since I don't think that it would matter much for the standards, and certainly not the way they are implemented, I would even be willing to live with a reasonable maximum estimate of the benefits, and make that information available to Congress.

DR. PARTRIDGE: Have you participated in any of these studies that you are advocating, these additional studies? Are you aware of any such activities and the results of such an activity?

DR. ZECKHAUSER: I haven't done them in terms of occupational health and safety. I have done them however in other areas. For example, I participated in a study that was published this spring on the risks, costs, and benefits of surgery and when we started that study we didn't know whether various surgical procedures were very effective or efficacious.

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[2459] MR. VAN VOORHEES: Your Honor, first we have Dr. Howard Maibach appearing on behalf of the American Petroleum Institute.

JUDGE LAWRENCE: Present your testimony.

DR. MAIBACH: My comments will be very succinct and limited to one simple issue, and that simple issue is how much, if any benzene, applied to the skin of man goes through the skin. In order to make some sense of the recorded data that is present to you in the literature, to anybody, I have taken the liberty of summarizing it into two parts, with interpretations of each.

The first part starts in 1897, and the second part starts in 1946. The first part in 1897 were attempts [2460] to determine how much benzene goes through your or my skin by applying the material to animals. Now, in 1897 when this was done, there was essentially no information available as to how the skin of a guinea pig or a rabbit differed from our skin other than the fact that we obviously share some dissimilarities in appearance.

The first observation was by Santeson in 1897. The material was applied to the rabbits. The rabbits had had their hair removed, and the skin of the rabbit changed under observation, and they questioned whether the material went through it.

The next observation was in 1925 when Morrow applied material to guinea pigs. The guinea pigs had their hair removed. Again, there were no quantitative estimates to determine how much went through, just to see if there was a change in the physical appearance of the skin.

For all practical purposes then, the first observation to try to determine how much benzene goes through the

skin was in 1931 when Lazarev and his associates did a simple experiment in which they immersed either the ear or the paw of rabbits or mice into benzene for some hours, and then they attempted to measure how much, if any, of the material went through the skin by looking for benzene in the breath with a colorimetric assay, and they came up with a figure, which has been [2461] published and quoted, stating that the amount of penetration was several milligrams per centimeter per hour.

I think that it is very likely that for the rabbit this is probably a very correct observation. The problems with extrapilating that to your skin or my skin is simply that the amount of benzene used was enough to "mummify" the skin, which is a very different situation than you or I working with benzene. Mainly they were dealing with very abnormal skin.

Next Leeman attempted to measure the penetration of benzene through the skin of animals and records that he saw no penetration.

The last animal experiment was by Petrilli in which benzene was applied to the skin of the guinea pig in a pack, and I will get into the significance of a pack, and "slight intoxication" was noted.

I think the most relevant experiments are those that started right after World War II in Italy, leaving the skin of animals and going directly to the skin of man, and the reason that I believe that this is relevant is that we now know that there are very grave differences and very important differences with man being superior to the animal.

If one wants to give it a teleological connotation, mainly that man has a skin that is able to [2462] keep chemicals out a great deal more effectively than many animal species, and certainly much more effectively than the rabbit.

The first experiment after World War II in man was done in 1946 by Cesaro. He did a rather heroic experiment, by many standards. He took some men who were volunteers, he removed their clothing and placed them in a tank. He then, in the tank, gave them a breathing apparatus so that their skin could be exposed. He meas-

ured the amount of penetration of benzene by using a technique of comparing the ratio of inorganic sulfates to total sulfates. Now this is a relatively crude method in 1977, and using that technique and applying the benzene both as a vapor and a liquid, and he doesn't explain how much he applied, he found that there was no penetration.

The next experiment was done by the people known as the Research Association of British Rubber Manufacturers. They took a somewhat different tack. Instead of just applying vapors they applied liquid benzene to the chests of the volunteers, and they examined both the sulfate ratios, the total sulfates, and they looked for benzene in expired air, and they too came to the conclusion that with their experimental technique and with the analytic techniques available in 1947, that they found no evidence of penetration.

[2463] We now go another few years. We go to 1956 when Konka and Maltigliotti did an immersion experiment. Here they took the hands of workers, immersed them, their hands and their forearms, in full strength benzene for 25 to 35 minutes. Again, they used as their analytic method the evaluation of breath, and they used the sulfate ratio method, and they too, again, came to the conclusion that under the circumstances of their experimental technique, in immersing the hands, they found no evidence of penetration.

The last experiment and the one that is the most important, because here a postive result is equally as important as a negative result, Hanke and his associates in 1961 did a somewhat different experiment. In 1961 they took some benzene, and unfortunately I have had to read this in translation because I don't read Czech and I have read the official translation provided to me, but what they did was they applied the benzene in cotton pads and then they applied a plate over the cotton pads. Using this, and using another technique for measuring penetration now, or as an index of penetration, namely the amount of phenol appearing in urine, they came to the conclusion that there was penetration of benzene in the subjects that they studied.

Now this experiment has two problems of [2464] interpretation. The first problem is that they were not measuring the penetration of benzene, they were measuring the amount of phenol, and the people that they were studying already had a fair bit of phenol in their urine, so one is stuck with the problem of trying to extrapolate how much of the phenol was present in these people before they started out, and how much was due to that added from the benzene.

The additional problem of interpretation here is very simply that Hanke, in 1961, didn't know that any time you take a piece of anything and you cover the skin with it and you wrap it with an impermeable dressing, such as the glass plate, you greatly alter the permeability characteristics of skin, and for those chemicals that we have data on, which is unfortunately not benzene, we know that it is one of the most potent methods of driving molecules to the skin.

You may know that dimethylsulfoxide is written up in many of the lay journals and scientific journals as an extremely efficient way of driving molecules into the skin. Well, dimethylsulfoxide is not nearly as efficient at driving molecules into the skin as that little piece of plastic or a piece of glass. So, the data that Hanke observed has the one problem of interpretation, how much of the phenol was due to the benzene, how much was due [2465] to natural phenol from other metabolic pathways and secondly, how does one extrapilate by his plate be applied over the cotton to the situation of the worker.

I would like to summarize both the animal and the human data by saying that in 1977 it is extremely difficult, if not impossible, to balance all of the information that is available. Admittedly, the overwhelming majority of the observations suggest that benzene does not penetrate the skin. One observation suggests that it does.

Today we have a much simpler and a much more direct way of answering this, and I would hope as the result of the deliberations of this congregation of observers and official party that in a very short period of time we could get a very specific answer because now radioactive benzene is available, and one simply would

apply radioactive benzene, some Carbon 14 benzene, to the skin of the arm of an appropriate animal that has permeability characteristics similar to the people in this room, and the monkey and the guinea pig, nor the rat would fit into that category, and then would simply look for the radioactivity excreted into the urine the feces and the breath.

This is a simple technique. It has been done for over 100 organic compounds in the last decade, measuring the amount of transport to the skin, and it would then tell us definitively, without argument, and efficiently, [2466] just how much of any benzene penetrates the skin.

Using the simple technique, it then would become possible to answer a number of other very relevant questions for people like yourselves responsible for making standards.

Question number one, is the material absorbed from the palms the way it is from the forearm or from the chest because there is a greater difference between the absorption of one part of your body to another than there is in all of the people in this room.

For instance, for some of the chemicals that have been measured, there is a 40-fold difference between one anatomical site and the other in man, and so I think if we are talking about standards for benzene, the site of the workers skin that is exposed certainly is a site that should be studied.

Secondly, a very critical problem that must be answered, in all of the data that has been provided to me, it is assumed that benzene applied to the skin has the same or equal toxic potential compared to benzene inhaled which is believed to be the major point of entry.

Well, I think in the 1940's this was a very reasonable assumption to make. In the 1970's, we are aware of a number of examples where the skin metabolizes compounds in an entirely different fashion than any other part of the body, and references are in my written testimony. So, [2467] therefore, once you start to do this and use modern analytic techniques, it should be possible to determine is the skin detoxifying or is the skin handling this in

a way similar to the lung, or is it handling it in a different way.

Next, we didn't know, until 1977 a very basic part of this story. In 1976 we believed that if you splashed a chemical on your skin once, or if you splashed a chemical on your skin ten times, we assumed that if you applied once and IX went to the skin, if you splashed it on ten times then 10X went through the skin. We now know, at least for one chemical, it is the only chemical that has been measured, that that, although it is a basic assumption of all dermatologic therapy, happens not to be correct, and the data for this is in my written testimony for the one compound.

So, in setting standards for benzene for workers, one would also want to know is there a difference in one exposure versus multiple exposures, and again, with modern analytic and biological technology, it should be very simple, very quickly, and inexpensively to answer this.

Another practical matter to be resolved is can one in fact protect you or myself or any worker with protective clothing. It is automatically ordinarily assumed that this is in fact the case, but until you do an [2468] experiment with the protective clothing, using appropriate methodology, one cannot make that assumption. It is very possible that you may be, but it is equally possible that it may not be, and it is something that can be demonstrated.

The last two things that one could measure very effectively today, within a period, I would think, of 12 weeks, and that is is the amount of benzene that is absorbed through our skin concentration dependent. Certainly, in broad range, it must be concentration dependent, but in the practical matter of setting standards, we do not know whether there is a linear relationship for all chemicals in terms of the amount of absorption.

Then lastly the thing that would be extremely germane to know in setting standards is that benzene is a very volatile material. When it is splashed onto the skin, is it going to evaporate more rapidly into the air or is it going to go into the skin more rapidly. I think all of these and several other questions could be very expeditously

answered if any of the appropriate agencies who are interested in setting the standard wish to obtain the data.

JUDGE LAWRENCE: Thank you very much, Dr. Maibach. Does the Solicitor have any questions?

MS. KALARIS: Yes, we have just a few questions. Dr. Maibach, you said that the evidence was not clear as to [2469] whether or not benzene is absorbed through the skin. What is your personal view?

DR. MAIBACH: Well, I appreciate a direct question, and I will give you an equally direct answer. I don't know.

MS. KALARIS: Thank you.

DR. MAIBACH: May I clarify you, because I think it is important to be in the record.

MS. KALARIS: Certainly.

DR. MAIBACH: I think it should be emphasized through normal skin of man rather than skin of rabbit. I think we must separate those.

MS. KALARIS: Would the rate of absorption of benzene be greater through the broken or the damaged skin than through the intact skin?

DR. MAIBACH: It is ordinarily assumed that penetration of any molecule will be greater through damaged skin than undamaged skin, but unfortunately I have to tell you that today that is usually as assumption rather than a fact, namely in many dermatologic situations where we are trying to drive molecules through the skin for therapeutic purposes, we have almost no background data to verify that assumption, and it could be that when we get the data, it may be very surprising.

MS. KALARIS: What is the basis for the [2470] assumption?

DR. MAIBACH: The basis for the assumption is that your skin is protected by an outermost barrier, the dead skin, the stuff that you see in the bath tub interferring with the soap, on the side of the tub, the carotene or stratum corneum. That barrier, that little dead layer of cells in fact is a perfect membrane for allowing you and I to get out of the seas. Namely, this is the membrane that keeps water in us.

It has been assumed, and it is certainly true, that if you remove that membrane, if you damage it, the water comes right out of you. It has been assumed, in fact, that it does the same thing for chemicals. Well, the little bit of analytic data that we have done suggests that when we move that barrier we only increase penetration for the few chemicals, and I don't want to generalize on this, about three-fold, and I told you that a little piece of Saran Wrap will increase penetration about 10-fold.

Stripping off this barrier increases penetration about as much as dimethylsulfoxide would, not as much as occlusion, and certainly there seems—whoever created us gave us other barriers to penetration, other barriers to protect us for chemicals going in, other than just the stratum corneum.

MS. KALARIS: Then liquid benzene could damage [2471] that barrier?

DR. MAIBACH: Liquid benzene could damage that barrier.

MS. KALARIS: Once the skin is broken, would multiple applications produce more penetration than a single application?

DR. MAIBACH: Last year I would have given the answer yes. This year, on the basis of the one reference of new data that I have given you, I don't know.

MS.KALARIS: And your answer would apply whether or not there was just splashing of the skin or there was drenching?

DR. MAIBACH: Would you kindly repeat that?

MS. KALARIS: You said you don't know, and this year you said you do not know the effect of a multiple application, and that would be the case whether or not there was just splashing, the application was by splashing, by intermittent contact with the skin, and would also be the case if the skin was thoroughly drenched?

DR. MAIBACH: I would still say that I think that experimental data must be obtained, because it is very practical information.

MS. KALARIS: Is there any data which shows that repeated skin contact does not result in absorption?

DR. MAIBACH: The only data that is available—
[2472] MR. VAN VOORHEES: Is that with benzene?
MS. KALARIS: With benzene, yes. Of course.
DR. MAIBACH: No, I don't have that data.
MS. KALARIS: Okay. Is benzene absorbed more readily if it is in another solvent such as to toluene or xylene, does it penetrate the skin more readily?
DR. MAIBACH: I found no data for or against that. Again, very easily measured in 1977.
MS. KALARIS: You mentioned a 40-fold increase in certain anatomical regions for some chemicals. What part of the body were you referring to?
DR. MAIBACH: Well, I was specifically referring to the scrotum. Every chemical that we have studied to date, using radio isotopes, and using man, suggests that the scrotum has essentially no barrier to penetration for many chemicals.

For instance, the first one that we studied was hydrocortisone. Hydrocortisone is very poorly absorbed, very minimally absorbed in the forearm. About 40 percent of the dose is absorbed in the scrotum.

Some of the pesticides that we have applied, 100 percent of the dose is absorbed in the scrotum.
MS. KALARIS: So other parts of the body would be less sensitive?
DR. MAIBACH: Generally speaking, we know of [2473] no area other than the scrotum that is completely permeable. I might add that the female genitalia have not been studied so we don't know the answer.
MS. KALARIS: You mentioned Saran Wrap increasing absorption from three-fold to ten-fold. If you are wearing a shirt, for example, would that shirt, if it is splashed or drenched with benzene, act as a Saran Wrap and increase the absorption?
DR. MAIBACH: The only data that we have bearing on this is with totally inclusive materials.
MS. KALARIS: Such as?
DR. MAIBACH: Such as plastics, rather than shirting. Shirting would be an entirely different—it would be a very relevant question to ask, but we have no background data to date.
MS. KALARIS: Thank you.

JUDGE LAWRENCE: Do we have any questions from the floor? Mr. Alexander?
MR. ALEXANDER: Thank you, Your Honor. My name is Victor Alexander, I am here on behalf of the Industrial Union Department of the AFL-CIO.
JUDGE LAWRENCE: Would you estimate your time?
MR. ALEXANDER: I will try to keep it within a half an hour, Your Honor.

Dr. Maibach, is there some standard way that [2474] experimenters use to apply an occlusive dressing? Can you describe that to us, in an animal experiment?

For instance, if you apply a piece of plastic or Saran Wrap, are the edges sealed?
DR. MAIBACH: Could you clarify a little bit? If I knew what you were driving at, I might be able to answer that.
MR. ALEXANDER: On page five of your statement, you say it is not clear whether the watch glass was used as an occlusive dressing, and I am just trying to get out if the fact that it was held down by an elastic which might have left the edges open for evaporation, if that would qualify as a standard type of occlusive dressing, as you understand it.
DR. MAIBACH: I don't have any ready answer for that.
MR. ALEXANDER: On page six of your statement, five and six, at the bottom, and then going over, you talk about them having performed 52 tests for the concentration of phenol, and that they found an average of 7.2 milligrams of phenol per liter of urine, and that this was the baseline observation.

Further down the page you say that the maximum concentration observed in the controls was 16 milligrams. Do you have any idea how those data were distributed? For [2475] instance, how many of them had values, say, above ten?
DR. MAIBACH: I don't really have a specific idea. I can give you the exact data.
MR. ALEXANDER: Good.
DR. MAIBACH: In translation.

MR. ALEXANDER: I don't read Czech either.

DR. MAIBACH: Here we are. This is page 10 of their Table Two, and it is entitled, "Maximum Values of Phenol Excretion in Urine in Unexposed Persons, and Persons Who Absorb Liquid Benzene Through the Skin", and the maximum concentration of what they call, in this particular table, "physiologic excretion", and it is 16.0 milligrams. One of their exposed subjects had 15.8.

MR. ALEXANDER: Excuse me a second Doctor, I was interested specifically in the controls.

DR. MAIBACH: Okay, they give, as the controls, 16.0, in this particular table.

MR. ALEXANDER: That was the maximum value?

DR. MAIBACH: Maximum concentration in milligrams per liter.

MR. ALEXANDER: You reported, on page six, that the average was 7.2 milligrams.

DR. MAIBACH: Okay, that could be a different table. The table that we are referring to there is their Table One, "Physiological Values of Phenol Excretion in [2476] Different Unexposed Individuals", and there were 52 tests with a result that they say test results from 3.0 to 16.0 with an average of 7.2.

MR. ALEXANDER: My question really relates to, in one case, at the top of page six here, you are referring to 7.2 as a baseline, and further on in your comparisons, you use 16 which is the maximum observed value for controls, and I ask you if it really wouldn't be more appropriate to consider 7.2 the baseline rather than 16.

DR. MAIBACH: It is a very germane question. I chose to use what the authors chose in their discussions.

MR. ALEXANDER: If, in fact, one were to do that, then the five values you report for the exposed subjects would then have concentrations of phenol in the urine on the order of two to three times as much as what I might call the baseline.

DR. MAIBACH: For that reason, I think if you and I were doing this, in light of standard experimental design, neither one of us would do it this way, would we? We would take each person as his own control because you would have to worry about outlyers, and if you

notice their table in which he gives his physiological excretion of 16, 3 of the 5 subjects were at baseline level. I think 2 were above it.

MR. ALEXANDER: At the maximum level for controls [2477] when you say baseline.

DR. MAIBACH: Right. So, obviously that made him a little uncomfortable too.

MR. ALEXANDER: On page 7 you state that the authors do not appear to eliminate the possibility that these two subjects, meaning the two that are above the so-called baseline represent a contamination from another source. I wonder if we were to apply the other version of baseline, if, in fact, it might not be a question whether or not the 16 value that was observed might not have been from contamination of another source. If you might turn that phrase on it's head, so to speak.

DR. MAIBACH: It is an interesting question, I don't have a good answer for it.

MR. ALEXANDER: You have written several papers about using a standard technique, which apparently you developed for studying both pesticides and other organic compounds. Is that correct?

DR. MAIBACH: Yes.

MR. ALEXANDER: If I can refer to one paper in particular, which is called "Absorption of Organic Compounds Through Skin in Man", it contains several interesting things, one of which, on this question of recovery in urine, after IV administration, two compounds which have some reasonable similarity to benzene, that is [2478] dinitrochloro benzene, and nitro benzene, those would be benzene compounds with some substitutions. In those cases, something on the order of 60 percent was recovered in the urine, and do I take it to mean that if a similar situation occurred with respect to measuring phenol, that we might be talking about an actual absorbed dose, something on the order of twice as much as they were actually measuring?

DR. MAIBACH: Yes, that is a very easy question to answer. If you measure—if I put some benzene on my—if I put some melathion on my forehead, and if I accounted for one percent of that being excreted in the

urine and stools, there could still be a very significant underestimate.

If I didn't know what happened when you put melathion into the body to be sure that in fact you could find it in the urine and stool, so we therefore correct or incomplete excretion after foreheadal dose.

MR. ALEXANDER: I wonder next what the effect of worker sweating would be on the absorption of a compound. Is it likely to be increased?

DR. MAIBACH: Unfortunately we only have one objective documented study on this work we did with a pesticide. It was either parathion or melathion, and it is unpublished work, but I can provide the experimental data. We found surprisingly no difference with the one [2479] pesticide we studied and one anatomical site, in one statistically significant experiment. The statistical significance was we could show no difference.

MR. ALEXANDER: That is a little bit surprising?

DR. MAIBACH: Like many things in membrane transport, once you get the data, it is often very surprising.

MR. ALEXANDER: Based on that, do you have any idea what the mechanism for the increased transport, when you are using an occlusive dressing would be?

DR. MAIBACH: We have pat answers that we give to students who are not very questioning. Do you want those or do you want the real answer which is I am not sure that we know?

MR. ALEXANDER: I wonder if some of the experiments that are described were conducted at 25 degrees Centigrade. I wonder if, for instance, in a working environment where the temperature might be 40 degrees, if that might have an effect to increase the transport.

DR. MAIBACH: If I understand your question, it is two parts. One, does the occlusion—

MR. ALEXANDER: No, I am not talking about occlusion. I am speaking about temperature.

DR. MAIBACH: There is every reason to believe on the basis of invitro studies, that increasing [2480] temperature will increase penetration, but again, as in all of these things, that is going to have to be documented with in vivo studies.

MR. ALEXANDER: How about the humidity? The experiments described discuss 35 percent humidity. It is relatively common to find an environment where the humidity might be 70 percent or higher. What would that do to the rate of transport?

DR. MAIBACH: I think that is going to have to be measured in vivo before I will be comfortable enough to answer.

MR. ALEXANDER: Now most of these experiments relate to compounds applied to the forearm skin, and in some of your published work, for instance, you say that skin, such as the angle of the jaw or the face would have a, based on the experiments that have been done, transport factor some four times greater. Is that correct?

DR. MAIBACH: The chemicals that we have studied, it is the general rule that the face is more permeable than the forearm.

MR. ALEXANDER: And the back of the hand, compared to the forearm, is perhaps twice as great?

DR. MAIBACH: We have very little data on that, unfortunately.

MR. ALEXANDER: In one of your papers also, you [2481] site an individual variation from person to person of five times in the amount of a compound. I think it was specifically pesticides absorbed. Do you have any reason to suspect that same sort of variation might not apply to the case of benzene?

DR. MAIBACH: I think we need the simple experiment to answer that.

MR. ALEXANDER: You also talk about—I understand the caution you are giving us about whether one dose or multiple doses, but you mention, again, in your paper, something about the effect that it is possible to have sort of an overwhelming dose in which there may be a linear relationship of absorption to concentration to a certain point, and then much more of the compound would be absorbed.

In the case, say, of a mechanic, who opens a pipe and is inadvertently soaked in the stuff, might not that be a case where you have this overwhelming event?

DR. MAIBACH: I don't recall having made a statement about overwhelming absorption. I wonder if you could clarify that for me.

MR. ALEXANDER: No, I didn't mean overwhelming absorption, I meant that there seems to be a relatively linear relationship between concentration and absorption up to a certain point, and then after that, more compound [2482] applied, a greater proportion of it might go through the skin.

DR. MAIBACH: Okay, I understand now.

MR. ALEXANDER: I was just trying to give a practical application of this concept.

DR. MAIBACH: There are purported examples in which the opposite occurs, namely at very high concentrations one gets less absorption than one gets at lower amounts, and I think you would have to obtain the data to know what would happen with benzene.

MR. ALEXANDER: Now, as I understand it, your standard protocol is to do a complete urine collection for five days, and you report for several different compounds, the pesticides for instance, half lives ranging from up to 28 to 30 some odd hours. Now, as I understand it, the standard practice would be to collect urine for at least three half lives to be certain of a reasonable collection over 90 percent, and based on that, since in the experiments you report, there seems to be an incomplete urine collection for a period of 24 hours, if in fact that might not be a significant understatement or the total absorbed dose.

DR. MAIBACH: One can plot that out mathematically, and we do, and in fact, on certain compounds, we have collected as long as 20 days. Hexochlorophene is one [2483] of them because of it's slow, half life in excretion.

MR. ALEXANDER: Also, if I understand some of your work correctly, you also speak about the fact that various layers of the skin can act sort of as depots, storage depots for the compound, and that this may explain some of this delayed absorption, but in fact, the compound may be stored in one or another of the layers, only to be released very slowly later on. Is that a fair representation of—

DR. MAIBACH: As a general rule, I would not know if that would hold with something like benzene.

MR. ALEXANDER: I guess I just have a couple more questions then. Again, in that paper that I was referring to earlier, you mention on page 400 that three compounds, possibly two toxic to test intraveneously in man or administered instead intraperitoneally in guinea pigs.

I wonder if you could tell us why you chose not to administer those compounds to man. The compounds, I believe, if I am reading correctly are butter yellow, malathion, and methylcholanthrene.

DR. MAIBACH: Butter yellow we chose not to apply, and I am thinking back a decade, and I would have to look at my notes.

MR. ALEXANDER: I appreciate that.

[2484] DR. MAIBACH: Butter yellow is a low grade carcinogen. Methylcholanthrene is the same, for the same reason. Malathion has, we subsequently realized, to be very easily administered to me intravenously,—

MR. ALEXANDER: So your concern with two of those compounds, at least, was the possibility of their having some carcinogenic risk.

DR. MAIBACH: Yes.

MR. ALEXANDER: Now, on page 11, your last comment is that similar studies could be safely done in man because the chemical and radiologic exposures are extremely small.

I wonder if based on this prior work of yours, and if in fact benzene has a carcinogenic risk, whether or not you might be concerned about conducting an experiment of that sort.

DR. MAIBACH: Well, at the time we wrote this, we were unaware of the fact that there is a very good animal model now for this, and so I would be very happy to run it as an animal model.

Secondly, we have learned a great deal more general toxicology than we knew then, and would feel very comfortable about injecting tracer quantities into myself for instance.

MR. ALEXANDER: The final question is, I [2485] understand that these experiments are done on human

volunteers, and I wonder whether the protocol for such a study has been submitted and approved by the human experimentation—

DR. MAIBACH: For benzene?

MR. ALEXANDER: Of your medical school.

MR. MAIBACH: These experiments have, but not for benzene. We have suggested in this that studies like this should certainly be done for benzene, either in an appropriate animal model, which would be the one of the species, monkeys, that we have correlated data with other compounds from animal to man, or certain—I suspect that this would probably clear many committees for the use because of the very small doses needed because of the exquisiteness of the analytic methodology available today.

MR. ALEXANDER: Thank you, Doctor. Thank you, Your Honor.

JUDGE LAWRENCE: Do we have any further questions from the floor? Mr. Wodka?

MR. WODKA: Five minutes, Your Honor. Dr. Maibach, the National Institute for Occupational Safety and Health has placed into the record here a 1972 German study by Hartwich. Are you familiar with that one?

DR. MAIBACH: May I take a look at it please?

MR. WODKA: Sure. Well, let me read to you [2486] this part of it. I don't have the entire study. I have a reference to it. What they did was this, they found an increased incidence of structural chromosomal aberrations in a group of nine refinery workers who did not have clinical hematological or biochemical abnormalities.

The concentrations of benzene measured in the individual outdoor working areas had at no time exceeded 25 parts per million. However, there had been prolonged skin contact with benzene with all the workers, and I would like to know if you think this observation is significant?

DR. MAIBACH: I am afraid that I am not familiar with that paper and would have to study it before I would comment.

MR. WODKA: Let me just show you this. This is the —one of the NIOSH references that was "Considera-

tions Bearing on the Question of Safe Concentrations of Benzene in the Work Environment", the MAK-WERT paper.

DR. MAIBACH: Thank you.

MR. WODKA: I have just excerpted some of the—

DR. MAIBACH: I would be very happy to step outside and read it and return after I have studied it, but I have not studied it before.

MR. WODKA: I just have one other question. [2487] I have listened here to your oral presentation, and I have noticed that in several places you stated that more work is needed in order to explore the question of skin absorption of benzene, and I think you expressed several places where more research is needed, more tests need to be done, and so on.

Don't you think, therefore, that it would be prudent for workers who are exposed to liquid benzene to wear gloves, impervious gloves, during this period of time while we don't have all the data?

DR. MAIBACH: That is a very direct question and the face of it is so simplistic is to be silly, and I don't think you meant it that way. Obviously, it makes a great deal of sense to protect all of us from all of the risks of the world, and I, like motherhood, must endorse it. However, I think the specific question that I am addressing myself to here is that whoever makes these standards does have a lot of practical issues to deal with, and this is one practical issue which is perhaps the most straightforward, namely how much of this material goes through skin, it could be answered before this committee's deliberations are finished. We are talking of a relatively short term experiment. In six to twelve weeks, one could have an enormous amount of data that could allow one to make some reasonable judgements without having to resort to the [2488] motherhood type of principle.

MR. WODKA: Well, I understand that, and I saw that in your testimony, but my question is if I, as a Union representative, came to you and said that I had a group of workers exposed to liquid benzene, and I was going to ask you, in your expert opinion, do you think

it would be prudent for me, as a Union representative, to insure that these workers wear impervious gloves when they handle up the benzene, what would you tell me?

DR. MAIBACH: I would tell you what I have been told by the people, the Union people who speak to me, and the workers who speak to me, and the State agencies that speak to me, namely that you must preserve your warnings with both you and me, whether it is smoking or anything else, to the most relevant warnings, and so I am saying that in the six weeks necessary to do these experiments, you will have your answer.

I don't think it is particularly effective to make a generic warning for everything, because then I think everything is disregarded.

MR. WODKA: So, in essence then, you would want to conduct your experiments first before you give me an answer?

DR. MAIBACH: I would like to, again, remove the first person from that answer, saying that I would be [2489] for you or anybody in this room who is interested in doing it, the techniques are straightforward and reliable, and it could be done by anybody having the analytic facilities available.

MR. WODKA: Thank you.

JUDGE LAWRENCE: Anybody have any further—

MR. WODKA: Do you want to hold on to that?

JUDGE LAWRENCE: Do you want to answer that question?

DR. MAIBACH: Would you like me to then write you or go out in the hall?

MR. WODKA: You could write me.

DR. MAIBACH: Okay. Fine.

JUDGE LAWRENCE: Do we have any further questions from the floor?

MS. KALARIS: Dr. Maibach, would you submit your opinion on that article for the record please?

DR. MAIBACH: Yes, I certainly will.

JUDGE LAWRENCE: Mr. VanVoorhees, do you have any questions?

MR. VAN VORHEES: I have just one question, Dr. Maibach. If an employee were wearing impermeable

clothing or gloves, and in the process of handling benzene, liquid benzene got underneath the gloves, would that increase the absorption potential of the benzene?

[2490] DR. MAIBACH: If benzene is like other chemicals that have been studied, and that must be demonstrated, the occlusiveness of the glove would be a very potent way of increasing penetration.

MR. VAN VOORHEES: I have no further questions.

JUDGE LAWRENCE: Thank you. Thank you very much, Dr. Maibach. Mr. MacDonald, do you want to be second?

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[2701] DR. WILSON: The corrections I have to make are mostly typographical. On page 18 of my testimony on line three the word "most" is typed and it should have been "worst". It is "under the worst case".

On page 24—

MS. KALARIS: Would you go a little bit slower, please?

[2702] DR. WILSON: Page 18 there is a typo and line three. It should be, "suggests that benzene is at worst a weak mutagen," not "at most".

MS. KALARIS: Yes.

DR. WILSON: On page 24, in the various tables, in all of these tables, that should read, for example, on page 24, it should read on the first number, it should be 10 to the power of minus 6. The minus 6 is put on the same line as the 10 in all of these typings and it should be read as a superscript.

On page 25, the third entry in the table, it is incorrectly typed. It should read five times 10^{-4}.

On page 29, line nine, there is a correction because here I was referring to the draft study, the Arthur D. Little, which was done for OSHA, and the final study has slightly different numbers in it. So that I will have to correct these statements here.

On line nine it said "Calculated in the above OSHA study," it is $75 million for 12 months plus $250 million capital cost, which, if I amortize at 10 percent, corrected for inflation, it gives a total of $100 million a year.

Then I would go on, "Corresponding to a cost of $300 million for every hypothetical life saved". Those are the corrections, the ones that I found.

[2703] I will give you a brief summary and try and put this in the framework that has already been mentioned. I would like to—well, I want to point out in my testimony what I believe is a necessity of making a risk estimate in any situation involving either the workplace or an environment, whether it is a carcinogen or not.

It seems to me that anyone who claims that benzene is a leukemogen or a carcinogen must put numbers into a statement and preferably numbers into the dose so that that automatically will give him some estimate of a risk no matter how rough it is and peoples' reluctance to make this estimate is, in some senses, to my mind, synonymous with a reluctance to believe that benzene is in fact a carcinogen.

Likewise, I believe that it should not make much difference to OSHA action whether benzene is found to be a carcinogen or not or merely a suspected carcinogen. OSHA, in its regulations, should be careful if it is a suspected carcinogen and should put reasonable limits on the dosage.

If it is found to be a carcinogen, there is no reason, in my view, and I can't see anything in the law either, that there should be a sudden switch in what it does and even though the emergency standard, the proposed emergency standard, in the preamble, said something about [2704] having to reduce to zero emissions, I believe that is not reasonable and one should make a risk estimate in both cases in order to properly protect the worker and if one insists on too low a risk, then one is not protecting other workers enough because one may be spending too much on protecting that one group and without any benefit to that group.

Now, the dominant feature, it seems to me, in the emergency standard as promulgated and as I have heard just a little bit of the questioning is the failure of OSHA to put numbers into a risk and to state what relation this proposed standard has to public health and particularly to health of the workers.

Without such a relation I don't quite see how one can usefully make a new standard.

Also, I want to emphasize that there seems to be no emergency involved here. We have been using benzene for 50 years. Indeed, we were using it at those levels far higher than we are now using it. There have been no dramatic cases of leukemia that have been standing out all over the place and in fact, as the evidence has shown, it is hard to prove that the cases of leukemia that have been seen are indeed attributable to benzene.

Therefore, a short delay, while we try and understand the situation, should not have catastrophic [2705] significance. This is not a new chemical and it should not be treated as such.

An emphasis has been placed on a simple yes or no on whether it is carcinogenic or not. This by itself I believe is nonsense, particularly in today's framework. 30 years ago when you had three carcinogens, radiation, cigarette smoking, and beta-naphthalamene, I think.

Now we have about 150 known human carcinogens and 1,000 animal carcinogens and if we were able to look with human beings with the sensitivity we can look in animal experiments, most of these animal carcinogens would, I think, be found to be human carcinogens.

Yet, the laws of science haven't changed. These things haven't suddenly become carcinogens. They were carcinogens before. That is just what they are now.

I suspect that if we improve our techniques we will find more suspected animal carcinogens and we have to be careful about that.

We can put them on a scale now and in fact table C of my testimony I put such a testimony which came from a paper of Mr. Meselson and I put some limits of benzene on that scale. We will see that at a worst it is a very weak carcinogen compared with the strong ones that we know how to deal with. We have examples. It is also a weak mutagen.

[2706] On a direct carcinogen, which we have heard about, mutagenesis, carcinogenesis, are usually related, and that was the point, of course, of Meselson's paper. Benzene is at least 100,000 times weaker than aflatoxin

as a carcinogen. Aflatoxin we regularly eat with the peanuts offered on American Airlines and Allegany Airlines and so on, and even available in the FDA cafeteria.

It is also a thousand times weaker than benzoapyrine which we regularly pour at our workplace and environments and kitchens and fossil fuel burning, from our cars and from charcoal burning foods.

Even if benzene is found to be a carcinogen in the end, at the level of the limits I took, I believe that OSHA should tackle the bigger hazard first. If indeed it is correct that OSHA wants to have a policy of stopping all carcinogens, they should stop smoking in the workplace, particularly all hearing rooms, OSHA cafeterias, and anywhere where people work.

They should also stop people working anywhere within a quarter of a mile of a car so that we don't have—which can be done. It is quite feasible. Maybe we should wear gas masks. I worked several days with a gas mask in the second world war as an air raid warden. Fortunately only in practice.

It is possible for us all to wear gas masks in [2707] the cities and it is feasible and that might be the technical meaning of the Act.

However, I think the right thing to do is to evaluate the risk, see if the risk is sensible. It is indeed, as I can testify. Wearing a gas mask does reduce one's availability to do work. I have done it in order to show that I could carry out my duties as an air raid warden while still wearing a gas mask. It was possible but a lot harder.

Moreover, you know, we can measure these substances and control them better than ever before. 30 years ago if we found a substance that was found to be carcinogenic it was not only potent but it was present in high concentrations.

The sort of policy that OSHA seems to be talking about today might have made sense 30 years ago. Nowadays we are finding weak carcinogens. We are finding them in low concentrations. To make an absolute statement, it is a carcinogen or not and making a change in rules in accordance is to my mind wrong.

So that we have to do—now early in the hearing Professor Zeckhauser testified and he quite correctly rejected putting a value on human life and his way of talking about cost effectiveness analysis. In my testimony I gave an example of how on a reasonable basis, pessimistic [2708] basis, on how benzene might be a carcinogen, this proposed standard, using the Arthur D. Little study, will cost about $300 million for every hypothetical life saved.

Spending that $300 million is not done without a waste of life. We know that every time you build a building lives are spent, about one for every $20 million spent in construction. Now, that $300 million won't all be in construction but a rough estimate suggests that the $300 million, three other lives will be lost. So for saving one hypothetical one we will have spent three. I believe that is not correct.

Now, the question therefore is we have to have a yardstick in order to compare risks and benefits. The public interest lobbying organization called The Federation of American Scientists in a study of carcinogenesis a year ago called for such a yardstick.

The Federal Register on May the 22nd last year, Russell Train, Director of EPA, said one should compare risks and benefits and said that is what they were supposed to do and mentioned it was the new change in policy. I hope they follow it.

It has been said—so, I think that is what OSHA should be trying to do in the hearing and unfortunately, it didn't come in the preamble to the proposed statement. The risk analysis that I try and present and the comparison [2709] with other testimony are rough ones because, as we have heard, the data on possible carcinogenesis is rather rough.

However, I think it is about the best one knows how to do.

So on the—if we take this conservative hypothesis one would then come to a feeling, I would come to a feeling, that although there may be some, a more careful study might show it in some places, one could reduce this standard below 10 parts per million without this huge expenditure which is in the Arthur D. Little report.

Incidentally, I would point out that is not an industry report. It is an OSHA-commissioned report. One would normally expect industry to be more pessimistic about how much it costs and an OSHA-commissioned report to be more optimistic. But this is the OSHA one.

So, in the Arthur D. Little report they do mention something in the latest copy about the possible benefits of this. But only in extremely rough terms. They make no estimate about making a risk study, no attempt to compare these risks with any other risks in society so as to give one perspective, and so that I believe this is a major defect in that Arthur D. Little study and in that I completely agree with Dr. Zeckhauser that these defects, although omissions in the Arthur D. Little study, are so [2710] great that some of the details which he and other people were also concerned about in that study are comparatively irrelevant.

I want to make one more comment. The Arthur D. Little study comments that the OSHA policy is that putting dollar costs on risks is arbitrary. I would certainly agree it is somewhat arbitrary. It is, however, done, as Dr. Zeckhauser commented in his testimony and I would just add on one more place where it has been suggested, and that is in the Nuclear Regulatory Commission hearings, the so-called "as low as practicable hearings" which lasted a period of two to three years and was finally ruled on last year where they suggested $1,000 for a man-rem of exposure which has a possible level below which one should reduce radiation exposure.

They reached this by taking the most conservative number that anyone had suggested to them and rounding it on upwards to be as safe as possible. If you take the same linear projection on cancer incidence that I took in my study, this corresponds to a number roughly of $10 million every hypothetical life saved and that is somewhat less than $300 million which I estimate that this proposed OSHA standard would take, according to the Arthur D. Little study.

So that I believe, in fact, that such numbers have [2711] been done in the Government, should be done again, in fact, should be done very much more than they have been in the past.

JUDGE LAWRENCE: Thank you, Dr. Wilson. Off the record.

(Off the record discussion.)

MS. KALARIS: I would like to advise everybody that we have in the back copies of page four, page five, page eight and page 10 of Professor Wilson's presentation.

JUDGE LAWRENCE: Page 30.

MS. KALARIS: Oh, that is page 30 of Professor Wilson's statement. Those pages were missing from some of the copies obtained through the Technical Data Center. So if you need them, they are out there in the back.

JUDGE LAWRENCE: All right, any further business? All right, there being nothing further, the hearing stands adjourned and we will resume tomorrow morning at 8:30 a.m. Thank you very much.

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[2721] MS. KALARIS: Would you explain please what you mean by a weak carcinogen?

DR. WILSON: Yes. If we look at my Figure 3 in my testimony, this comes from the work of a colleague of mine, Matthew Meselson at Harvard University. Now he was very much impressed, as a lot of people have been, that in a very large number of carcinogens, which were found to be animal carcinogens, there is a direct proportional relationship between the ability of this chemical to produce revertance in a mutagenic test of the type of Bruce Ames at the University of California. The relationship between if you do a study on animals where you do a lifetime study of feeding of this particular carcinogen, and this graph is taking to those cases where a lifetime study is available on animals, and there is also a mutagenic study available.

It is quite significant in my mind that over a range of approximately 10,000, some chemicals produce more [2722] mutation activities than others by a factor of 10 to 100,000. Those same chemicals that are more potent in producing mutations are also more potent in producing cancer.

For example, on this curve the most potent one on the curve, I am not sure it is the most potent carcinogen we have—I don't think so, is aflatoxin B_1. That is in very small quantities it is known to produce cancer in animals. Two parts per billion will cause according to the NIT of that study by Jerry Wogan, will give 10 percent of the rats cancer. Whereas if you do similar tests, for example, on benzopyrene, whereas a test here is on Chinese hamsters, you would find you would have to have a 30 to 40 times the concentration of the chemical to get the same number of rats dying. If you do the same test on saccharine, you will up the curve at the top right hand corner, you will have to have a dose of 7½ percent of saccharine in the diet, fed continuously, in order to produce 15 percent cancers.

So there is a very wide range, well over 100,000 into the factor between the potency of some carcinogens and others. These are, I would like to note, what one might call direct carcinogens.

If benzene is a direct carcinogen, I put on this graph where it might lie because if it is a direct carcinogen, it would presumably show up on an Ames Test. It hasn't [2723] according to the information I have from the people in Bruce Ames' lab. It has been tested, and they haven't found anything. They haven't found anything, I don't accept a yes or no as an answer to this sort of question.

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[2732] MS. KALARIS: How do you define an insignificant risk, Dr. Wilson?

DR. WILSON: Oh, the only way of regarding a risk as insignificant, in my view, is very much a personal question, and it has to be by comparison with others. That is why I have always, in my own mind, I have not been content with calculating risks of anything until I have compared it with something else. Something else particularly without getting involved with personally if possible and something else which I can calculate on as nearly as similar basis as possible. Then if one risk is very much smaller than the other, say it was less than 10 percent, then I would tend to regard it as insignificant.

MS. KALARIS: On Table I you have calculated risks for certain occurrences.

DR. WILSON: Table I? Yes, there it is.

MS. KALARIS: All right. What relevancy does that sampling of risks have to the risk of developing leukemia from occupational exposure to benzene?

[2733] DR. WILSON: That has less relevancy than some of the later tables, but it—incidentally I have just realized there is a misprint on line 2 of that, my division can't possibly be correct. Excuse me, I have line 2 with a risk from falls of 17,000 people must be 9 times 10^{-5} and not 9 times 10^{-10}. I must beg your pardon because it is clearly the total number divided by.

The relevancy, to go back to the relevancy question, these are risks which various elements are exposed to it in various ways. Some are exposed to some and some are exposed to the other. I personally try to avoid the risk of firearms, I am never able to avoid the motor vehicles or the falls or the fires or the eletrocution for example. Those are risks to which we are all exposed to in life. Now I would normally, the two aspects of which this is a risk we ought to expose to whether we work on a subject or not. If benzene work on an ordinary person, you would have that risk.

Now risk of benzene is a risk in the working place. A risk that is usually accepted, and I would think it reasonable to continue, that if a limited number of people in a limited occupation can be exposed to slightly higher risk due to that occupation, than the general public. There are a wide number of cases; otherwise without that you would clearly have the obvious cases, climbing a scaffold, [2734] fix a building. That is clearly a very risky thing to do. You clearly stop the general public from doing it, you don't let them get up there. But you nonetheless ask a worker to do it. So that is not directly applicable to worker, but it is so that should in general those risks that you would expect you would allow a worker have a sightly larger risk than those ones that he is generally exposed to in that sense.

But those are just to give a perspective and nothing much else.

MS. KALARIS: Thank you.

(Pause)

MS. KALARIS: Isn't the significance of a risk relative? For example, in your written testimony, you cite the example of no one reasonably worrying about being killed in a hurricane. Now this might be true in the United States, but it may not be true in another country where hurricanes are an annual hazard. So isn't it a question of selection of priorities?

DR. WILSON: Oh, absolutely. Risk is certainly right to question. Of course, there are numbers on hurricanes in the United States which is also very important to note that although a hurricane is widely defined to be an act of God and of course in that sense it is. Nonetheless you can protect against it and reduce your risk, and a [2735] cautious person would look, in fact it is quite notable the people who calculate risks in this business of calculating risks, calculating them will in fact start avoiding hurricanes and choosing their airlines rather carefully and so on.

MS. KALARIS: Would you agree, then, if one's prime objective is to protect as many workers as possible, one may not be willing to accept a risk which entails a few workers being exposed to a hazard?

DR. WILSON: I am sorry, I don't understand the question.

MS. KALARIS: We said that, if I understood you correctly, you agreed that risks are relative.

DR. WILSON: Correct.

MS. KALARIS: Ok. If one's primary objective is to protect as many workers as possible from a particular risk, one may not be willing to accept the risk which entails few workers being exposed to the hazard. In that case doesn't the risk become a significant risk rather than an insignificant one?

DR. WILSON: I am still not quite sure to understand it but let me try to answer and see if I have got it correctly.

There is a prime objective for protecting human life, that is correct. In the framework of this hearing, [2736]

one can talk about that limit that particular groups of people who are working people. Now indeed risk is a variable question and as I said, it is somewhat an individual question. It is important not only to make sure that the risk to all of society be small, but there is no individual group in society which is unfairly being called upon to shoulder a very large section of the risks. I believe that that is perhaps what you were trying at in that question. I would agree with that that you should not ask one limited section of people to take unusually large risks merely for the benefit of the rest of society without some concomitant benefit for these people or giving them perhaps the opportunity of rejecting that particular option of accepting that risk.

I will give an example. We all know that being an astronaut is a very risky business. Quite apart from the risk of the thing failing and exposed to cosmic rays and radiation at a level far exceeding the ordinary industrial level. Approximately one trip to the moon is 20 times the yearly dose for an occupational worker. The astronaut is asked to shoulder that risk. They shoulder it willingly; they would have an opportunity declining. Although they are exposed to a larger share of risk than anyone of the general population, I don't think it is unreasonable.

MS. KALARIS: On Tables III & IV, would you turn to [2737] those please? You state that on the basis of these tables, occupational exposure to benzene presents an insignificant risk. Are the risks calculated for these tables all hypothetical risks?

DR. WILSON: No, they are not. Some of them are real. Some of them are known. Let's see.

MS. KALARIS: What —

DR. WILSON: —Some of them are rather certain, and the ones on benzene are hypothetical and may be overstated.

MS. KALARIS: Ok. What did you hypothesize? Or what assumptions did you make in calculating the risk of benzene?

DR. WILSON: Oh, I went back. That is back on several pages back. That is a fairly normal, if I may go through the assumptions I made.

Starting with Figure 4, my Figure 4, I tried to make sense out of this highly discorded set of data. As I plot the data, I put various dotted lines on it. I have tried to assume that no one was completely wrong; that no one was actually lying or anything like this, but there was some misinterpretations of some parts of the data. Mr. Aksoy, for example, he found twice the standard cancer in Turkey, 13 parts per thousand. It is possible he missed quite a few cases so one can, I didn't put it on the figure, but one [2738] might assume as Pat Faulker that twice as many cases is the dose level I thought was 200 parts per million. I believe he stated that. Faulker could clearly have missed some cases and one could go upwards on that. I was not quite sure what to make of recent NIOSH study. I had assumed as had Dr. Tabershaw gave testimony yesterday, that he was talking about these cases being 15 parts per million. I am not quite sure that he still holds to that, but we looked at it last night.

It doesn't explicitly say. Anyway, I was guessing that he had understated it, and that was more like to be 100 parts per million or even some different chemical. Because otherwise it is very hard to make sense of that data and at the same time assume that there aren't too many shoemakers left in Turkey. Vigliani's data, I assume, was slightly high.

So I took the bottom curve on this, bottom line, the risk liner 1.8 times 10^{-6} per year at one part per million dosage. That is the slope of that line. That probably what the data really is assuming a straight line instance. That is saying a straight line is pessimistic.

I could have taken one of the other lines with this discordant set of data, but I was reluctant to admit that everyone in Turkey was going barefoot. Then I said I have seven other cancer case in tobacco smoking, for [2739] example, we all know that the first case we found was lung cancer. Yet that there are lots bladder cancers we now come across, perhaps twice as many cancers as the number in the final cite. So I doubled that risk and brought it up to 3.5 times 10^{-6} at one part per million.

Now, this would be risk—Oh, this risk by the way is

slightly overestimated risk, because that is by taking the ratio to the normal instance.

Now if you look at, now the one reason for taking the ratio to a normal instance is to save myself work, and to use the work that other people have done. Because when you want to calculate the normal instance, you have got to complicate age correction on what the age of the people concerned with. I didn't want to go through that work, but the people who have done these studies have done that work. By taking that ratio, you can factorize that part out.

Now, this risk then becomes correct if people were exposed to this benzene not only their working life but until they die. But in fact, they are not exposed to the benzene for age 65 to age 80, and it is quite likely therefore the risk is overstated by a fact of two. Nonetheless, I have left that stand. So that number, 3.5 times 10^{-6} per year at one part per million becomes 3.5 times 10^{-5} per year at 10 parts per million. That is I calculated that risk.

[2740] DR. WILSON: I don't know that benzene might be a direct carcinogen. If it is a co-carcinogen only, then it is wildly overstated.

MS. KALARIS: Doctor, what is the risk at 10 ppm as compared with the risk at one ppm?

DR. WILSON: According to this way of calculating, it will be 10 times as much. Incidentally, that is one of the advantages of taking a linear calculation. Everytime people plan to do risk calculations and do these general calculations; Dr. Pochin, myself, other people; we always try and assume over a wide range there is a straight line curve.

If you don't do this, the calculations become tricky. It becomes much harder to visualize them, and so on, and so although this is perhaps overstating the benzene figure, I believe if you want to do public policy on a risk calculation basis, this is a fairly prudent and slightly conservative thing to do.

MS. KALARIS: Thank you. On page 28 of this statement, you assume that 30,000 people are now exposed to three ppm benzene concentrations.

DR. WILSON: Yes, that was—

MS. KALARIS: Can you explain the basis?

DR. WILSON: Yes.

MS. KALARIS: For the level assumption?

[2741] DR. WILSON: Yes, I was taking this report, the report of Arthur D. Little for OSHA. Now, the page number I have got here, Page six, second paragraph, was from the preliminary draft of this, and I must apologize. I only got the final thing a couple of days ago, and I should have updated that page reference.

But they say in there somewhere, and it was page six, second paragraph, that the standard would effect 150,000 people, and only 30,000 of these now have concentrations above one part per million.

I tried to get out of that study a number, a sort of graph of who is exposed to what. Maybe it is in there, but I didn't find it. It is not very clear. It seems to me perhaps a weakness, it is not clear. I shouldn't be grumbling about a report not being clear because many of mine aren't either, but I couldn't find that so I made the estimate; there is clearly going to be some distribution. They won't all be at the top. So I made a very rough guess that they were three parts per million.

I believe that if you are to do this job properly, you are supposed to improve my risk estimate and go over this rather carefully and probably do a complete integration over these numbers, but I am trying here to pull in what is, I believe, a major gap in the justification [2742] OSHA had for what they are doing, what they are proposing, and outline the method by which OSHA would do it.

MS. KALARIS: On page 29, I believe you stated that only a few 100 people would be regularly exposed to 10 ppm of benzene concentration. Can you explain the basis of that statement?

DR. WILSON: That is maybe incorrect. It came out of a page in this report here, and again, they were vague on this particular question. Therefore, I am a little vague on it. Probably, as I was thinking about it last night, I think a few hundreds; it is probably closer to 1,000 than 100, but I really don't know.

* * * *

[2753] DR. LLOYD: Dr. Wilson, on page four, the paragraph on the [2754] page, you say, "I wish to make it clear that, of course, we did testify. I satisfied myself that benefits should be included. The manufacturing of benzene at ten parts per million level up-graded the potential risks associated therewith." I would ask, benefits to whom and risks to whom?

DR. WILSON: Okay. I possibly answer that question, of course, just now. There is a point here which your question brings out, that in fact, the potential risk will be to the benzene worker. It is going to be in my view a considerable benefit to society. There is an important feature in any one of these cases, as in fact in all cases where anyone that is employed in any sort of occupation riding a bus or an aeroplane that some measure of this benefit be passed upon individual workers, and there are various ways of doing it in society.

A classic way in a really dangerous occupation, which this isn't, is giving a worker hazard pay, but this is no way near that. But this has to be born in mind.

DR. LLOYD: And then you do that since in comparison to other risks which society regards as insignificant. Would you say that that little worker is insignificant?

DR. WILSON: Pardon?

DR. LLOYD: Would you say that the death of a [2755] worker is insignificant?

DR. WILSON: The said the risks can be insignificant. I have never regarded death as insignificant. I can regard a risk as insignificant, but not a death.

DR. LLOYD: Well, then, what are you referring to when you say, "Society regards them as insignificant." What do you mean by "insignificant"?

DR. WILSON: "Insignificant" in this case is much less than other—"Insignificant" would be in this regard a risk which in most people's ordinary calculation of what to do from one day to the next, you would not take account of even if you were aware of the details of the calculation.

DR. LLOYD: Is that what we are talking about here when we are talking about workers who died from leukemia?

DR. WILSON: I am sorry. That is what I was talking about on page five. Indeed, that is why I think the main important feature is my table, Table Three and Table Four. I think Table Three is particularly important. It is particularly important, it seems to me, to make sure that society is not asking a worker in a benzene factory to shoulder a risk which is appreciably greater than risk in any other occupation.

That is the reason why I listed some of these.

* * * *

[2772] DR. LLOYD: When you said you estimated the risk of the benzene-leukemia problem, you described it as inspired guesswork.

DR. WILSON: No. I think it is—in one direction it is a guess. In the following sense: I have, we have some data. It is a lousy set of data as we have had several times during this hearing. It is data on the interpretation of which people have disagreed, and now I have made a estimate, I think it is slightly better than a guess, on what the risk might be. Now you might—it is open to other people to disagree, but the reason why I think that it is more than a guess is, for example, suppose I was to assume that the latest NIOSH study of Infante and Young and people was literally correct and was five times the normal instance at ten parts per million of benzene. [2773] And I was also to assume that there was a plot which was approximately linear and no worse than linear between effect and dose. I see no reason why it should turn over. Then it would be very hard to say why at two hundred parts per million you would not just be getting five times the normal instance, you would of course have to be getting one hundred times the normal instance. As I said before, I just don't see how there can be a shoemaker in Turkey left. And although I know, no doubt, there are some people in Turkey that go without shoes, I don't think everybody does.

And therefore, I don't believe that it is merely guesswork. It is correlated. Trying to correlate this piece of information, trying to explain—that is why somewhere in here I may have said it is very hard to take that study

completely literally. Of course, I must say that I made an error in my reading. I don't think they said that those cases were ten parts per million. There may have been some sort of implication there, that I thought there was. If there are higher figures, or in fact due to other chemicals, then that could be the explanation of that figures. It is hard to say that it turned out not to be benzene at that dose level. It might be, but that would be very much upsetting all the indications that we have got.

* * * *

[2820] MR. MACDONALD: Your Honor, we do know that Dr. Aksoy has done extensive industry research.

DR. WILSON: I knew that and I forgot that.

DR. LLOYD: You have made reference a number of times to Dr. Aksoy and to shoemakers. In reference to your statement that all of the shoemakers in Turkey should be dead on the basis of the Infante estimate—

DR. WILSON: Yes. No. Not on the Infante estimates but upon the estimates of the Infante Study if they were at 10 parts per million.

DR. LLOYD: I realize what you are saying. Now, couldn't it be that with benzene we might have a situation analogous to what we have in beryllium and with asbestos where the people who are at the very high exposures show an acute disease which is not presented as cancer as is presented in beryllium and asbestos and it turns out in the end result when we look at these patients that the people who have the long latent disease are people who got essentially lower exposures. Couldn't that be the case with benzene? Particularly in light of Dr. Aksoy's report with so many of the shoemakers dying from their blood dyscrasia.

DR. WILSON: What you are suggesting to me is that there might be really different dose-response curves for this particular case?

DR. LLOYD: Yes.

[2821] DR. WILSON: It is conceivable, I suppose, that any dose—response curve is possible. I would— It would be a rather unusual, almost I think, revolutionary contribution to the literature on cancer to have a dose-response curve on cancer.

DR. LLOYD: You agree with what I am describing is true for beryllium and for asbestos?

DR. WILSON: Well, beryllium is not a carcinogenic in this way.

DR. LLOYD: It is not a carcinogen?

DR. WILSON: Not in this way. I mean it is not a direct carcinogen. I don't know that it is direct. The people I know who had beryllium poisoning have not died from a carcinogen. It does not have the carcinogenic properties. They have mostly died of ankylinicosis which is not a carcinogen.

DR. LLOYD: Are you going to be attending the beryllium hearings?

DR. WILSON: No.

DR. LLOYD: I would suggest you do.

DR. WILSON: I haven't time to attend all hearings and still try and understand what is going on in one or two of them.

DR. LLOYD: Now in reference to insignificant [2822] risk when talking about risk as a personal guess in compared to other things and how you do this yourself relative to matters like jumping off—

DR. WILSON: That is right.

DR. LLOYD: Do you know whether in general workers exposed to benzene, or for that matter, any person, were ever given a chance to make such a conscious choice?

DR. WILSON: Yes. Some workers are. I don't know if all workers are. A person is given—certainly in the radiation field which I know a little more than in the carcinogenicist's field. A person who is employed is told that he is a radiation worker and told to carry a film badge and can deem to accept this job or you can accept it if you wish. And you can take another job, maybe in the same company.

[Exhibit 2-46 (list of references omitted in printing)]

OSHA TRANSLATION

OSHA-76-62

Med Lavoro
46:194-198, 1955

STUDY OF THE PERCUTANEOUS BENZENE ABSORPTION

By

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We believe that a study of percuteaneous benzene absorption is timely; accordingly, we performed a series of experiments in man, involving direct contact with liquid benzene, i.e., the tests were implemented under conditions which actually reproduce those forms of contact which occur during industrial use.

For a prolonged period of time—we may safely say ever since the professional study of benzene pathology started—various authors investigated the possible penetration of the toxin through the cutis surface.

The characteristics of the substance which is a powerful lipid solvent, soon led to the assumption that benzene with its significant lipolytic properties active at skin level, could break through the protective cutaneous barrier; it was suspected that the substance enters the circulation over that path and disperses in the organism.

Santesson was first to investigate the problem experimentally in 1897. His tests were performed in rabbits with the application of pure benzene pads on the shaved cutis. He reached the conclusion that benzene absorption does occur.

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[2] Later Mauro, Lazarew, Brussilowskaja, Lawrow and Lifshitz, expressed analogous opinions, always on the basis of animal experiments.

Mauro used guinea pigs, placing pure benzene packs on their cutis and leaving these in place for two hours every second day. Introducing an alternative of the Santesson method, depilation was used instead of shaving the guinea pigs so as to avoid abrasions through which benzene might penetrate.

Lazarew, Brussilowskaja, Lawrow and Lifshitz experimented with rabbits, soaking a paw in a pure benzene bath and attempting to prevent the animals from inhaling vapors originating from the bath.

In a monographic study on solvent pathology, Lehmann and Flury contested the conclusions reached by the above authors. They found instead that no cutaneous absorption could take place, nor would the absorption be of any interest in practice; they limited the question to an exclusively theoretical level.

Petrilla conducted interesting research work in laboratory animals. He tested 15 guinea pigs, in part with intact fur, in part after mechanical or chemical depilation. The animals were subjected to benzene evaporation involving the cutis of the entire body, excepting the head. The presence of intoxication symptoms was verified in almost all animals, including some guinea pigs with intact fur. The last-mentioned animals showed, after 6 days of testing, cutaneous modifications as well as macroscopic changes such as hyperemia, edemas and chapped skin lesions. The author interpreted the results by confirming the possible capacity of benzene to transgress the cutaneous barrier, even when said barrier is intact.

More recently, Nunziante Cesaro showed interest in the problem. This [3] author refers to experiments performed in man. Individuals with perfectly sound cutis were placed for a period of 20 to 30 minutes into a metal tank in which the atmosphere was saturated with benzene. The head of the test subject was kept outside through an opening in the tank; a rubber tube linked to a face mask provided inhalation of vapor-free air. The dosage of the urinary sulfate derivatives was determined

before, immediately after, one hour after and two hours after the start of the experiment.

The practically unchanged SI/ST ratio and the absence of benzene in the air led the author to the conclusion that percutaneous absorption does not take place, at least not when the cutis is perfectly intact.

Subsequent investigations resulted negative as well; they involved the application of cotton wool layers saturated with benzene on the upper limb cutis of some test subjects. The limb was kept for 20 to 30 minutes in a sealable sleeve. No benzene was recovered, not even in traces, from the exhaled air of this second test subject group.

Based on the total opinions stated in literature, the conclusion can be reached that two diametrically opposite views exist, both supported by a considerable number of authoritative researchers.

However, early experiments performed in animals are readily subject to criticism because the applied techniques either fail to guarantee the perfect integrity of cutaneous surfaces in contact with benzene, or do not strictly exclude possible inhalation of the toxin. On the other hand, under close scrutiny even research in man does not prove to be entirely convincing.

In our opinion, the principal objection against the work of these authors concerns the use of air saturated with benzene and the use of pads saturated with the solvent; these contact methods can be defined as "indirect".

[4] Said methodology can be justified by the attempt made to preserve the test subject from any morbid symptoms, including their cutaneous forms; the method nevertheless results in a questionable solution of the problem since (said method) is incomplete.

We do not believe—even from a purely theoretical viewpoint—that it is actually suitable to investigate possible percutaneous absorption of a liquid such as benzene in contact with the skin of a worker by using vapors in saturated form or by extending the contact over the entire body surface; physiologic knowledge concerning cutaneous permeability does a priori exclude any absorption in that form in case of lipo-solvents as well.

The above objection essentially also applies to the use of cotton wool saturated with benzene, placed on the cutis of a limb in a sealed sleeve. Under such conditions a transient and incomplete contact with the liquid solvent will evidently occur; but, since benzene evaporates rapidly, it will never be present in a volume sufficient for eventual absorption, and the result will merely be a vapor-saturated atmosphere in the sleeve.

For the above-mentioned reasons our research work was based on different criteria.

We selected test subjects, including a female, to evaluate the effect of individual cutaneous characteristics. The tests were performed on alternate days.

Direct contact with the toxin was accomplished by immersion in "commercial" benzene of the type used by a large factory manufacturing rubber articles. Maximal contact duration was limited to 25-35 minutes because already after a contact duration of 5 to 10 minutes from the start of testing the exposed cutis surface became intensely and increasingly painful; the [5] pain was characterized by a burning sensation.

The following technique was applied (see the photographic description of the instruments):

The subject introduces a hand and 2/3 of the forearm into a metal tank supported by a tripod; the surface of the tank has an opening fitted with a rubber sleeve and can be completely sealed; a face mask with double valve is then applied to the subject who starts to inhale, through a long rubber tube, air from the external environment. This protects against vapor inhalation during the test. Benzene is introduced in to the tank through a tube attached to a suitable container.

Towards the end of the testing period a hog bladder with an approximate capacity of 3 liters is attached to the exhalation valve of the mask; it becomes thus possible to collect an air sample and verify whether it contains any benzene vapors.

[Figure 1 omitted in printing]

We used two methods to determine the eventual percutaneous penetration [6] of benzene. With these methods, the elimination of the toxin from the organism can be controlled, i.e., the dosage of urinary sulfa derivatives can be determined and the presence of benzene in the exhaled air can be investigated.

We applied the Folin gravimetric method to determine the urinary sulfa derivatives. We took urine specimens before and two hours after terminating the experiment when—according to various authors—the elimination of sulfa derivatives, caused by the absorption of benzene, is maximal.

For benzene verification in exhaled air we used the following procedure: the air exhaled by the test subject during the final minutes of the experiment is collected in a hog bladder, it is subjected to effervescence (bubbling) with the use of a suitable pump (Orsat apparatus) in a solution constituted by 10 cc of H_2SO_4 and 1 cc of 40% formaldehyde. The presence of benzene in the bubbling air causes brownish-red discoloration of the solution, which is colorimetrically compared with a solution sample containing 1% nitroprussiate of sodium. With the aid of a suitable scale, benzene concentration in the exhaled air is determined from the number of pumping strokes (pompate) needed to obtain a coloration similar to the color of the control sample.

The obtained results are shown in the Table, see next page.

On the basis of these results we exclude the possible percutaneous penetration of benzene under the testing conditions adopted by us, i.e., with intact cutis, by means of contact between liquid benzene and a limb surface including the hand and two thirds of the forearm, during 25 to 35 minutes.

The above statement is confirmed by the collected data, primarily by the constant absence of benzene, even in minimal traces, from the air exhaled [7] by the subject at the termination of the experiment; secondly, the above is confirmed by variations of urinary sulfa derivative excretion which do not exceed physiologic fluctuations con-

[Table I omitted in printing]

sidered normal (Vigliani and Gemelli: maximal daily variation = ± 7; hour by hour variations = ± 2).

Moreover, we found that none of the tested subjects complained during or after the experiments about disorders of a general or local type which could be interpreted as benzene intoxication symptoms; nor were alterations or lesions of any kind found on cutis surfaces exposed to contact with the toxin.

We therefore share the opinion of researchers who contend that the penetration of benzene into the organism through the skin is impossible and [8] that the problem is not significant for practice. The penetration did in fact prove to be non-existent, even when testing methods were applied which involved direct contact maintained to the limit of the test subject's sensitivity, according to systems which do not only reproduce, but even emphasize systems used in industrial practice.

SUMMARY

An experiment was carried out to study the possibility of benzene being absorbed through the skin. Three sound men were subjected to the immersion of their hands and forearms in commercial benzene for 25-35 minutes. Urine sulfates were then determinated and researches made for benzene in the expired air. No benzene was found in the air expired by the subjects at the end of the experiment; no modification was noted in the inorganic-total urine sulfates ratio. The possibility of a percutaneous passage of benzene in the experimental conditions adopted is therefore rejected.

[Exhibit 2-47 (listing references omitted in printing)]

OSHA TRANSLATION

OSHA-76-60

Med Lavoro
37:151-56, 1946

IS PERCUTANEOUS BENZENE ABSORPTION POSSIBLE?

By

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(Director: Prof. Enrico C. Vigliani)

Percutaneous penetration is mentioned among the penetration modes of benzene into the human organism. We refer to Santesson (1897) (Ref. 1), who was one of the first researchers to state that such a possibility definitely exists. His experimental research was carried out in rabbits to the cutis of which pure benzene packs were applied after removal of the fur; the packs were kept in place with bandages. Subsequently (1925) Mauro (Ref. 2), obtained a similar result when testing chemically depilated guinea pigs: packs of pure benzene were applied for 2 hours each for two days. Said author, while never able to verify death among these animals, observed modifications of the morphologic-hematic aspect, a definite indication of starting intoxication.

Lazarew, Brussilowskaja, Lawrow and Lifschitz (Ref. 3) kept the paw of a rabbit immersed in a benzene bath, while preventing the animal from inhaling vapors originating from the bath; they likewise determined the presence of benzene in the exhaled air and therefore reached the conclusion that percutaneous absorption of the solvent is possible.

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At variance from the above, K. B. Lehmann and F. Flury (Ref. 4), in [2] their monograph on solvent pathology, state that the penetration of benzene through the cutis should be considered from a theoretical standpoint only, since they were never able to determine the percutaneous absorption of the toxin chemically.

Recently, the problem was re-examined by Petrilli (Ref. 5). This author experimented with five groups of guinea pigs. Each group included three guinea pigs weighing 450 to 600 g each. The five groups differed as follows: No. 1 guinea pigs with intact fur; No. 2 fur sheared off with scissors; No. 3 depilated with a razor; No. 4 depilated with chemical agents; No. 5 control animals. Benzene was applied to them by means of vaporization while the animals were sealed in appropriate devices; their heads were kept outside of the environment containing the vaporized solvent. The overall result of the investigation revealed that the animals of Groups No. 1—of primary interest here because they were intact—showed slight intoxication symptoms on the 4th day; but only two of the three animals were affected. The author states that the animals showed cutaneous changes on the 6th day, evident to the unaided eye, such as hyperemia, edema, scaly skin lesions; he believes that benzene is able to break through the cutaneous barrier, even in some cases when said barrier is intact.

A critical evaluation of the research work carried out by the cited authors prompts us to divide their work into two groups; the first includes Santesson and Mauro's studies and the second those of Lazarew, Brussilowskaja, Lawrow and Lifschitz and Petrilli.

The investigations of Santesson and Mauro are of considerable interest insofar as these authors were among the first to provide some data on slow benzene intoxication. But the possibility cannot be entirely excluded that [3] the animals on whom the benzene packs were applied might have inhaled the toxin. Therefore the work of these authors cannot be taken into consideration for the purposes of present study. On the other hand, said authors mainly intended to investigate the first symptoms of slow benzene intoxication.

The research work of Lazarew, Brussilowskaja, Lawrow and Lifschitz and of Petrilli are subject to criticism insofar as it cannot be ascertained whether the cutis of the animals treated by them were entirely intact. In fact, Petrilli found macroscopic cutaneous lesions already on the 6th day of treatment, while the first slight intoxication symptoms appeared only two days earlier. The possibility can therefore not be entirely excluded that cutaneous lesions caused by fur shaving or by the prolonged effect of benzene on the cutis—while roughly determinable only—could already have been active during the days preceding the appearance of the initial symptoms.

* * * *

Since the actual status of the problem had reached this point, we believed that a study of the question would by useful, also in view of the authoritative statements made by Lehmann and Flury.

We used men free from skin lesions as test subjects. A few days before the experiment, we prescribed a diet rich in carbohydrates (bread, potatoes, etc.) and green vegetables. The diet contained very little protein, so as to reduce matter causing intestinal putrefaction to a minimum.

Each test subject was placed nude into a metal tank for 20′ to 30′. The tank had a capacity of 8,317 mc and was perfectly airtight. The head of the subject remained outside, for which purpose the tank lid had an aperture; rubber sleeves prevented the escape of air from the inside of the tank to its exterior, and sealed the aperture through which the subject's neck was [4] passed. Moreover, after closing the subject's nostrils with a clasp, a mask was applied. The subject breathed through the mouth, using the 5 meter-long rubber tube fitted to the mask, and inhaled air originating from a courtyard beyond the chamber where the tank was located; the tube passed through a window. A benzene-saturated atmosphere was obtained in the tank by introducing several cotton wool pads soaked with the solvent. Furthermore, the subject applied liquid benzene to his skin within the tank, using cotton wood pads, also saturated with the solvent (see Fig. 1).

[Figure 1 omitted in printing]

Urine eliminated before the subject was placed into the tank, eliminated immediately after placement in the tank, one hour and two hours later was used for the determination of total inorganic sulfates with the aid of the Folin gravimetric method.

[5] We wish to premise, so as to justify the research work and sulfate dosage as well as the ratio between inorganic sulfates: total sulfates, that the research work of Yant, Schrenk, Sayers, Horwarth and Renharth (Ref. 6), Yant, Schrenk and Patty (Ref. 7), Gueffroy and Luce (Ref. 8), Vigliani and Giannini (Ref. 9), Girino (Ref. 10), Vigliani and Gemelli (Ref. 11) showed a rapid and significant decrease in the ratio between inorganic sulfates and total sulfates. As a consequence of benzene absorption, the first diminish while the second increase. The modifications reach their maximum two hours after the termination of the test subject's exposure to benzene vapors.

Urine sulfate dosage determination is carried out with the Folin method, which we will briefly describe here.

INORGANIC SULFATES.—25 cc urine is filled into an Erlenmeyer of 200 to 250 cc; then 100 cc H_2O and 10 cc HCl, diluted in H_2O with a volumetric ratio of 1:4 is added. 10 cc of an aqueous 5% $BaCl_2$ solution is added drop by drop during continuous agitation with a glass rod. The mixture is left standing for one hour; filtration of the same follows through a Schleicher-Schull filter (blue band); the filtration is carefully accelerated, using a vacuum bottle connected with a water pump. The filter is burned in a porcelain crucible which had been accurately weighed; the crucible is kept at a temperature of 700 to 800° for a couple of hours. Cooling follows in the desiccator and a final exact weighing is performed.

The weight difference in mg is the (weight of) inorganic sulfates contained in 25 cc of urine.

TOTAL SULFATES.—25 cc urine and 20 cc HCl, diluted as specified above, are filled into an Erlenmeyer of 200 cc capacity. Boiling for at least 20′ follows, while the Erlenmeyer's outlet is covered with a crucible slide [6] (vetrino da crogiolo) which has the overall function

of cooling, heating and regulating the boiling process, moderating the same to prevent the desiccation of the container.

The container is then cooled under running water for 2′-3′; 50 cc of H_2O is added; then 60 cc of 5% $BaCl_2$ is added drop by drop during continuous agitation with a glass rod. The next steps are similar to the procedure followed in case of inorganic sulfates.

[Table omitted in printing]

[7] Our investigations show that the ratio inorganic sulfates, total sulfates was not significantly modified as a consequence of cutis exposure to benzene vapors and simultaneous cutaneous application of the liquid solvent. The observed slight variations are within the limits of fluctuations found in normal subjects, since the S.I. : S.T. ratio is near-constant at various hours of the day; fluctuations generally do not exceed ± 2%. (Vigliani and Gemelli). (l.c.).

In addition to the examination of urine sulfates, we also investigated the benzene content of air exhaled by the same test subjects. For this purpose, the apparatus suggested by the British Home Office was used, previously tested in this Clinic by Vigliani and Reina (Ref. 12). The apparatus proved to be suitable for the determination of minor solvent volumes in the exhaled air as well, and it is suitable for the qualitative verification of traces.

The apparatus consists of a mechanism to activate bubbling of the exhaled air through a solution of formalin in concentrated sulfuric acid. The presence of benzene causes brownish discoloration of the solution, which is more or less accentuated. The color is comparable to a test tube containing a 1% solution of sodium nitroprussiate. Starting from the air volume needed for bubbling, so as to obtain a color equal to the sample color, the benzene concentration in the air is determinable with the aid of a suitable calibration table.

The examination of benzene in air exhaled while the test subjects remained in the tank and while their cutis was exposed to benzene vapors and kept in contact with liquid benzene, always resulted negative.

Another investigation involved the application of ample cotton wool [8] layers soaked in pure benzene on the

[Figure 2 omitted in printing]

cutis of an upper limb of all test subjects. These remained on the limb which was kept in a cardboard tube, sealed at its end and perfectly airtight, fitted with rubber sleeves (see Fig. 2). During the final minutes of the test, for approximately 20′ to 30′, the possible presence of benzene was examined in the air, with the aid of the above-mentioned method. Not even traces of the solvent could ever be determined nor recovered in any of the performed experiments.

In view of our experiments, we can therefore exclude a percutaneous absorption of benzene, at least to any appreciable extent, through intact cutis.

SUMMARY

An investigation was performed to determine whether benzene absorption through the intact cutis of man is possible. The cutis of the trunk and the limbs of 8 sound subjects were exposed for 20′ to 30′ to contact with [9] benzene vapors and liquid benzene, with the aid of instrumentation which excluded any eventual solvent inhalation. The absence of significant inorganic sulfates/total sulfates ratio modifications and the absence of benzene vapors in the exhaled air led us to conclude that no benzene is absorbed, (at least not to any appreciable extent) percutaneously by man, provided that the cutis is intact.

We reached the same conclusion from negative results obtained during benzene verification in the air exhaled by the men, following application of cotton wool layers saturated with the solvent in the cutis of an upper limb which was kept airtight in a perfectly sealed cardboard tube with rubber sleeves.

[Exhibit 2-69 (list of references omitted in printing)]

OSHA TRANSLATION

OSHA-76-56

Med. Pracy
12:413-26, 1961

ABSORPTION OF BENZENE THROUGH THE SKIN IN MAN

By

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It is generally understood that many organic substances have the ability to be absorbed through the undamaged skin. The function of the skin as a path of absorption is strongly emphasized—or on the contrary, omitted—mainly according to the extent of accumulation of clinical data on intoxication which were caused by the absorption of the given toxic substance through the skin. In regard to benzene, the view is generally accepted that it has the ability to be absorbed through the skin, but to an extent which does not induce intoxication. It is also accepted in practice that the sole essential path of benzene absorption under industrial conditions is the lungs.

Due to the expanded use of benzene as a solvent in some sectors of production and the appearance of cases of chronic intoxication, the question of the function of the skin as a path of absorption has once again become urgent, both from the standpoint of prophylactic activity and in consideration of the need for elucidating the clinical symptoms of absorption which have been observed (R. Vlasak, 1959).

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Current information on the absorption of benzene through the skin is primarily based on two research studies whose results were contradictory.

Lazarev, Drussilovskaya and Lavrov (1931) conducted tests on rabbits and [2] mice. Contact of the skin with liquid benzene was accomplished by immersion for several hours of the animal's ear or paw in liquid benzene. The amount of benzene absorbed they considered the quantity of benzene in expired air, as determined by burning to CO_2 and subsequent conductometric measurement of the absorbing solution. The rate of absorption of liquid benzene was determined at 0.05 mg/cm²/min (i.e., 3 mg/cm²/hr). With this rate of absorption it had to be taken into account that the authors, in not analyzing the excretion of benzene from the body through other paths, considered the absorption rates obtained as underestimated values.

The authors themselves also studied the absorption through the skin of animals of benzene vapors, protecting against their absorption through the respiratory tract. As an indication of absorption, the reference concentration of phenol in the urine was adopted: it increased in animals under examination. The results of the test were interpreted by positive quantitative methods.

Two arguments militate against the mechanical transposition of the results of this study to humans working in contact with benzene: a) the method of administering benzene to the animals induced profound changes in the physiological stage of the skin, leading to total mummification of the exposed portion of the body. The results of absorption obtained under such conditions may not be interpreted as absorption through undamaged skin; and b) it must be assumed that there may exist certain differences between the permeability of the skin of animals and men, linked to the differences in anatomic structure and skin function.

For the above reasons, the question was raised again by N. Caesaro (1946) who ran tests on humans involved with both the absorption of liquid benzene and its vapors. In the case of liquid benzene, he wrapped the arm in a cotton compress saturated with benzene. Adopted as the

measure of benzene absorbed: [3] a) the amount of benzene vapor in expired air; b) analysis of a drop in so-called sulfur ratio* in the urine. Both factors produced negative results, from which the author concluded that benzene absorption through the skin did not play a role in industrial exposure.

In that study, a limitation was indicated by the benzene absorption factor, since it is understood that it is analyzed with low sensitivity. A definitive drop in the sulfur ratio occurs primarily during absorption through the lung of benzene vapor in concentrations close to the industrial norm, i.e., about 0.1 mg/liter**. The negative result of sulfate tests can not be considered as sufficient negative proof in a discussion on benzene absorption.

Teisinger and Fiserova-Bergerova (1955) developed an interpretation to evaluate benzene absorption based on the analysis of phenol in the urine in man. This factor is very sensitive and permitted perception of changes in phenol excretion in the urine owing to the absorption of trace quantities of benzene.

The goal of this study was a quantitative analysis of the rate of absorption of benzene through the skin in man, wherein it was attempted to evaluate the role of the skin as a path of absorption of benzene under industrial conditions.

The following criteria of absorption were used in this study:

1. Determination of excretion of phenol in individual urine fractions at least one day long; interpretation of results obtained according to data of Teisinger and Fiserova-Bergerova.
2. Chemical analysis of the amount of absorbed liquid benzene by the method described below, developed specially for that purpose.

[3a] Tests conducted included:

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* As a result of binding of phenol into sulfuric acid esters, the amount of ester sulfate in the urine is increased at the expense of inorganic sulfates, causing a drop in the total sulfur ratio, which under physiological conditions, constitutes from 75-95%.

** This normal is now usually considered high; GOST allows a concentration of 0.02 mg/liter ever since 1959.

a) absorption of liquid benzene administered either with aid of insulated plate or using a slide (according to method of evaluation employed);

b) absorption of benzene vapors through the skin, where excretion of phenol in the urine is used as an indicator.

RESEARCH METHODS

1. DIRECT ANALYSIS OF BENZENE ABSORPTION THROUGH THE SKIN

[4] A method was developed which may be used in testing the rate of absorption not only of benzene, but also of other volatile solvents. The principle of the method does not deviate from that previously used in our institute for studies on less volatile compounds such as aniline (J. Piotrowski, 1957) and nitrobenzene (J. Salmowa and J. Piotrowski, 1960). An accurately measured amount of the substance is applied to the skin, making contact there for a specific period of time. By analyzing the excess of the substance in terms of a final test the amount of absorbed substance may be determined from the difference and thereby the rate of absorption. So far, a condition for the use of this method was the careful protection against losses occurring from the evaporation of liquid during the test.

In the case of benzene, protection against evaporation by means of insulation has been inadequate in view of its high volatility. An innovation of the new method is the use of the volatility of the compound being studied as a basis in analyzing absorption.

This method is carried out as follows: a small amount of benzene (0.02 ml) is applied by microsyringe to a watch crystal which is then pressed to the skin of the forearm with an elastic. The glass is placed under a funnel having a slightly larger diameter which, with the aid of short elastic connection pieces is connected to a water suction pump through a rinsing machine with a porous glass containing 20 ml of nitrating mixture (10% ammonium nitrate in concentrated sulfuric acid) as an

absorbing solution. This system is under a stream of cleansing air which washes the glass at a rate of 0.5-1 1/min (Fig. 1).

When the test is over the rubber connecting the glass and the forearm is cut through, permitting rapid evaporation of benzene; a 15 minute passage of air through the rubber gash is sufficient for total evaporation of excess [5] benzene and flushing the system with air. Individual phases of the procedure are illustrated in Fig. 2.

[Figures 1 & 2 omitted in printing]

Similar tests have been conducted on the same glass unit (without use of an exposed person) to establish a reading which corresponds to the amount of benzene applied. Benzene absorbed in the rinser in the form of m-dinitro-benzene is analyzed absorptiometrically with acetone and lye. For this purpose, the contents of the rinser are put aside until the following day to permit complete nitration, after which it is diluted to 1 liter with distilled water. Twenty milliliters of an aqueous solution are taken from the flask after thorough mixing. [6] The results of analysis with the same glass unit corresponds directly to the amount applied. Quantity of benzene remaining on the glass and skin after absorption test is calculated from the model:

$$m = \frac{A \cdot m_o}{A_o}$$

where m_o is the amount of benzene applied to skin, mg;

A_o is the sample absorption in test made on glass unit;

A absorption of sample in test on skin.

The amount of benzene absorbed ($m_o - m$) we divided by the glass surface (cm^2) and the skin contact time (hours). The result obtained is expressed as a rate of absorption ($mg/cm^2/hr$). The appropriateness of the procedure was verified in a way that the measured quantity of benzene was applied to the glass and brought in contact with the skin, after which contact was complete and it evaporated. In this way, we obtain an approximate exposure time $t = 0$. The results of this procedure did not show any difference versus analysis with

the same glass unit, due to which it was included in method calibration.

The precision of the quantitative analysis of benzene is ± 5%. The error is mainly the result of the final absorptiometric method of analysis, with whose aid no better results could be obtained. In view of the insufficient accuracy obtained here for a single measurement, the following conditions were stipulated to attain unambiguous results;

1. The test is run so that the amount absorbed is about 20% of the amount applied. Under those conditions we obtain a difference in findings (before and after) which is quite great; and the excess amount of substance on the skin does not alter the results of absorption to a significant degree. Consequently, the amount applied on the skin had to be reduced to a minimum, which in turn necessitated us to reject the plates used previously for tightly fitting slides.

[7] 2. Absorption readings for the initial applied amount of benzene were obtained many times to reduce the concomittant error, and as a basis the average was used, its error constituting a mere ± 1.4%.

3. The results obtained in the absorption of benzene through the skin were not interpreted individually, but an average result was adopted whose mean error is sufficiently small (in this test ± 2%).

Due to the conditions observed above, the research findings described hereinafter can be considered to be totally reliable.

2. ANALYSIS OF BENZENE IN THE AIR

In addition to the above methods, and during analysis of the concentration of benzene vapors in the air of the test room, the absorptiometric method with acetone and KOH was used in the Piotrowski modification (1954). Analyses were performed on a Coleman Junior spectrophotometer at a wavelength of 570 millimicrons. As stated, accuracy of analyses with the aid of this method was ± 4%.

3. ANALYSIS OF PHENOL IN URINE AND PHYSIOLOGIC VALUES

To analyze phenol in the urine, the colorimetric method with 2,6-dibromoquinonochloroimide was used in the version described in Teisinger et al. (1956). In this method, the phenol is analyzed after distillation from the urine from an acid medium as total phenol (free or esters).

In the initial tests it was found that the amount of reagent in the formula is insufficient to achieve conformity with Beer's law over a sufficiently large range of phenol concentrations. For 50 micrograms of phenol, this relationship is illustrated in Fig. 3. On the basis of the chart in Fig. 3, the amount of reagent was fixed at 0.25 ml and the entire analysis had the following procedure:

[8] 5 ml of urine to be studied with addition of 0.5 ml concentrated sulfuric acid is distilled in a glass apparatus (slides) with water vapor at a rate of up to 10 ml/min to obtain 50 ml of distillate. An optimal quantity is taken from the distillate (2.5 - 10 ml) and placed in a 25 ml flask; 2.5 ml of buffer (pH 10.15) is added (10.5 g $Na_2CO_3 \cdot 10\ H_2O$, 2.8 g anhydrous borax dissolved in 0.5 liters water) and 0.25 ml of alcohol solution of 2,6-dibromoquinonochloroimide (15 mg/10 ml), filling with water to make 25 ml; after 1 hour, readings are made on the Coleman Junior device (cell 25 x 105 mm; wavelength 610 millimicrons).

Calibration of the method * was done in the range up to 30 gamma of phenol in the sample; accuracy of analysis ± 6%.

[Figure 3 and Table I omitted in printing]

[9] The results of phenol in the urine analyzed by this method in different persons are illustrated in Table I.

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* In this example in the cited study of Teisinger et al., to make up specimen solutions of phenol (page 74, paragraph 1), theoretical error crept in; the solution made according to this formula would have a concentration not 10, but 25 gamma/ml.

COURSE AND RESULTS OF TESTS

1. ABSORPTION OF LIQUID BENZENE

A. STUDY OF THE RATE OF ABSORPTION BASED ON EXCRETION OF PHENOL IN URINE.

Five tests were carried out as follows: persons were exposed on the bare forearm* and a plate with benzene-saturated cotton was placed on the forearm (about 0.06 g/cm²). This plate was insulated with the aid of cellophane affixed to the forearm with adhesive tape. The contact area was 35-45 cm², contact time 1.25-2 hours. To eliminate absorption of trace quantities of benzene vapors (from the plate) through the lungs, the forearm was placed under a hood with an intense crossflow of air. In addition to a digestorium, the air was analyzed for its benzene content for purposes of control; the results were negative.

The urine samples were taken for an entire day, every 1-3 hours, and less often at night.

Excretion of phenol in the urine. In these tests, phenol excretion in the urine was low; daily amounts of excreted phenol ranged from 8.0 to 14.7 mg, which only slightly exceeds average values, and is completely within the boundary values of physiologic excretion given by Teisinger et al., (average 8, maximum 20 mg/day).

The physiologic values obtained by us were expressed either as concentrations (mg/liter) or as rates of excretion (mg/hour). The extreme values ob- [10] tained in tests on absorption are presented below, in comparison with the extreme physiologic values obtained by us (Table II).

[Table II omitted in printing]

As can be seen from Table II, the maximum rates of phenol excretion in persons exposed to benzene were much higher than the corresponding values confirmed by us. An increase in phenol excretion in the urine after

* Data are from self-experiments and from research on volunteers at the Institute of Labor Medicine.

exposure showed up most clearly in a comparison of the excretion curves (example given in Fig. 4). In this figure three curves of changes in phenol concentrations in the urine and the rate of excretion of the urine itself (A) are plotted, and their product being changes in the rate of phenol excretion (B); the latter curve appears to be most typical.

Although the very fact of increased phenol excretion in the urine after exposure to liquid benzene through the skin seems to be indisputable, a proper calculation of phenol surpluses caused by absorption of benzene runs into many problems. It is associated with the very great variability of physiologic values (example in Fig. 5). Taking the rate of excretion before exposure individually in each person as the standard, is quite impossible to the small number of such measurements; the average value before and after the test is slightly exaggerated, since we only have data obtained after the passage of [11] one day, when excretion is likely to not have reached physiologic values; adoption of the mean value established in most data from different individuals is impossible since the average (0.24 mg/hour) is much higher than the average from data obtained in persons exposed before the test (0.16 mg/hour). Certain arguments can be given in favor of using each of these methods.

[Figures 4 and 5 omitted in printing]

[12] It was found that the results would have less error if physiologic excretion was calculated as the average of all four methods of calculation. The results obtained thus are presented in Table III.

[Table III omitted in printing]

For a basis of evaluation of the amount of absorbed benzene, Teisinger et al. (1956) were followed in that the average of about 30% of absorbed benzene is excreted in the urine in the form of phenol. On that basis the rate of absorption of liquid benzene through the skin was calculated in individual cases (Table IV).

The average rate of absorption of liquid benzene through the skin, calculated in this way, constitutes about

0.24 mg/cm²/hour. In view of the number of assumptions made in the course of calculation, this value should be taken only as a reference value.

On the periphery of tests on phenol excretion, primary data was gathered on the characteristics of excretion of this metabolite. We were interested in the rate of excretion which was characterized by a constant K equation of the first order. The calculation was done on the basis of statistically calculated equation of regression (Fig. 6). Excretion constant is approximately 0.12/hour, on the average; and this is on the same order as the constants of excretion of metabolites of other aromatic compounds studied (p-aminophenol in application [13] of aniline or nitrobenzene; p-nitrophenol in the application of nitrobenzene to test animals). This value should be interpreted as referential, since it was calculated on the basis of too meager data and for very small doses of benzene. It is not precluded that phenol excretion is dual-phased, wherein the drop in the rate of excretion would be faster in the first stage: but the data we have is too meager and too one-sided to document this hypothesis in a manner which would not be suspect.

[Table IV omitted in printing]

B. ANALYSIS OF THE RATE OF ABSORPTION OF LIQUID BENZENE THROUGH THE SKIN BASED ON DIRECT CHEMICAL ANALYSIS

The method of test performance was done as described. Watch crystal used had an area of 8 square cm; contact of benzene applied to the glass (0.02 ml = 17.6 mg) with the skin lasted 1.25 hours. A total of 15 calibration measurements and 7 absorption measurements on the forearm skin were made in different persons. Calculation based on the data illustrated in Table V.

The average surplus of benzene from the watch crystal, caused by absorption of benzene through the skin, was:

$$x = \frac{0.110}{0.490} \cdot 17.6 \text{ mg} = 4.0 \text{ mg}$$

The average rate of absorption, with respect to area and time of contact, was:

[Figure 6 & Table V omitted in printing]

[14]
$$v = \frac{4}{8 \times 1.25} = 0.4 \text{ mg/cm}^2\text{/hr}$$

The results obtained by the direct chemical method (0.4 mg/cm²/hour) and the indirect method based on phenol excretion in urine of persons exposed (0.24 mg/cm²/hr) are quite comparable. From the standpoint of methods, however, we feel that the first of them (0.4), using the direct method, is quantitatively more sure. It should be noted that the results pertaining to the rate of absorption of liquid benzene through the skin refer to the extreme case, where the skin of the exposed individual is completely dampened by benzene at the point of contact; these are thus maximum values.

[15] 2. ABSORPTION OF BENZENE VAPORS THROUGH THE SKIN

Tests on the absorption of benzene vapors through the skin were done in a special toxicology chamber designed for this type of experiment (Dutkiewicz, 1960).

A total of three tests were run. The concentration of benzene vapors was 1.0 mg/liter; control analyses were made every hour and they showed that concentrations did not vary by more than ± 5%. The air temperature in the chamber was 25°C, and humidity was about 35%. The test subject was placed in the chamber without clothes. Before and after exit from the chamber, the test subject took a bath. To prevent contemporaneous absorption of benzene vapors in the respiratory tract while spending time in the test chamber, the person breathed pure air through a mask attached inside the chamber.

Evaluation of absorption of benzene vapors through the skin was based on analysis of phenol excretion in the urine. Urine samples were taken for one day before the test to establish physiologic levels of phenol in the urine. Then urine was taken during and after completion of exposure, also for the period of one day.

The results were evaluated on the basis of the amount of phenol excreted in the daily quantity of urine, considering the physiologic excretion established before the experiment in the given individual.

In the first test, exposure lasted 1.5 hours; no increase in phenol excretion was detected in the exposed individual's urine.

In two subsequent tests, exposure was extended to 7 hours. The increase in phenol excretion over the course of a day constituted 2.7 and 4.2 mg, respectively. For an average quantity, about 3 mg phenol per day, the likely amount of absorbed benzene is about 10 mg. This quantity is quite negligible, [16] if we consider that at the same concentration of benzene in the air (1 mg/liter) and pulmonary ventilation of about 3 m^3/7 hours*, the amount of absorption through the lungs would be about 1500

* In sitting position, without additional exertion.

mg**. Thus absorption of benzene vapors through the skin is less than 1% of the amount absorbed under the given conditions through the lungs. This quantity is small enough to warrant the conclusion that benzene vapors do not tend to be absorbed through the skin.

DISCUSSION OF RESULTS AND CONCLUSION

The rate of absorption of liquid benzene through the skin in the case of total moistening of the skin of the forearm with benzene in men is about 0.4 mg/cm^2/hr. This rate is of the same order as was found in previous studies for aniline and nitrobenzene. But, considering the relatively lower toxic effect of benzene as compared to those compounds, the rate of absorption of liquid benzene should be considered low. It is also essential that single moistening of the skin or clothes with benzene does not cause, in view of its great volatility, prolonged danger to the skin, as occurs in the case of aniline or nitrobenzene. Furthermore, protection of the skin against absorption of benzene should not offer any problem, with the exception of some jobs.

We should note that on jobs where moistening of the skin is continually renewed, e.g., in manual painting with paints containing benzene as a solvent, and in work of similar type where contamination of the skin with paints might furthermore be a comparatively persistent container of benzene, the absorption of benzene through the skin might play a more substantial role. Assuming that the area of both palms is 600 cm^2, the maximum amount of absorption in the course of 8 hours of work might be about 2,000 mg. This quantity would still [17] not cause acute intoxication, hence the lack of data on acute benzene intoxication through skin absorption. At the same time, it is very serious from the viewpoint of chronic intoxications. We feel that current increased tolerable concentration of benzene vapors in the air of 0.1 mg/liter effective in Poland is related to absorption of just about the order of 300 mg per day*, and the concentration per-

** Considering retention in the lungs about 50%.

mitted by GOST (0.02 mg/liter) is about 60 mg. Thus absorption of liquid benzene through the skin in manual work can not be neglected, as least as an additional path of absorption.

Absorption through the skin of benzene vapors is not, it would seem, any toxicologic problem.

(Authors thank U. Neuhorn for technical aid in carrying out research).

SUMMARY

The absorption of benzene throughout the skin in men in experimental conditions was examined. The liquid benzene was absorbed with the velocity about 0.4 mg/cm²/hr; the absorption of the benzene vapors was insignificant and it did not exceed 1% of this absorbed throughout the respiratory ways in the same conditions. The study was based on the determination of phenol contents in urine and on the new direct chemical method for the designation of skin absorption of benzene, the method described in the paper.

The authors concluded that the absorption of benzene throughout the skin must not be neglected.

[Exhibit 41-28]

Executive Office of the President

COUNCIL ON WAGE AND PRICE STABILITY
726 Jackson Place, N.W.
Washington, D.C. 20506

Dr. Eula Bingham
Assistant Secretary for
Occupational Safety and Health
Administration
Department of Labor
Room S-2315
Washington, D.C. 20210

Dear Dr. Bingham:

I am writing to offer comments for the public record on the proposed benzene exposure standard. The Council's basic concern with inflation, of course, motivated these comments which are detailed in the attached appendix and briefly summarized below.

At the outset, I am pleased to note one significant improvement which distinguishes this proposal from other recent OSHA health regulations. Less emphasis than usual is placed on engineering controls as the required means of compliance. The proposal allows firms to select any mix of work practice controls and engineering controls which will keep benzene exposure levels below those specified in the standard. By proposing some flexibility in approaches to compliance, OSHA is creating desirable incentives for firms to find the least costly means of protecting worker health. As explained in our attached comments, we think OSHA should move even further in this direction.

We are troubled, however, by certain other aspects of this proposal. We think the proposal does not reflect sufficient consideration of the costs and attendant health benefits of the standard. Given the inadequacies of

OSHA's Economic Impact Analysis (which we discuss in the appendix), we think the economic feasibility of this proposal has not yet been demonstrated. For example:

1) Compliance costs for a major sector of an industry (facilities for bulk and terminal storage of gasoline operated by independent wholesalers) have been excluded from the total compliance cost estimate. The EIA separately puts this sector's compliance cost at $4 billion but then disregards that cost on the grounds such facilities would be phased out of service in the face of this prohibitive cost. It seems unreasonable to imply that forcing wholesalers out of business or dispensing with the service they provide is without cost to society.

2) Costs to tire manufacturing and related industries are understated. The EIA assumes substitutes will be found for benzene which will make unnecessary any capital outlays for engineering controls. Yet there is no discussion of the cost or availability of suitable substitutes.

We also think the proposal and its EIA lack adequate analysis of alternative exposure levels and implementation plans, as more fully explained in the appendix. For example:

1) There is no discussion of using the "action level" approach employed in other health regulations. Such an approach could (a) provide an extra margin of safety, (b) make unnecessary the present proposal's exemptions (such as gasoline distributors and industries using liquids containing very little benzene, where workers could conceivably be exposed to hazard), and (c) lessen certain recordkeeping and measurement costs.

2) In work places where the per person cost of exposure reduction is particularly high *and* where exposure is of a sporadic nature, some consideration should be given to alternative, less costly methods of assuring protection. Yet the feasibility of such alternatives, such as the use of respirators, is not carefully addressed in the proposal or the EIA.

3) We also wonder if OSHA has estimates of the incremental reduction in health risks which are associated with the reduction in exposure levels from 10 to 1 ppm.

On balance we think the proposal is not yet ready for adoption. We urge OSHA to improve its economic analysis of the proposed standard and to revise the proposal so it will assure worker health protection at the least possible cost to society. We think this can be accomplished without excessive delay, and in the interim vigorous enforcement of the existing emergency temporary standard can serve to protect worker health from the dangers of benzene exposure.

If you or your staff would like to discuss this further, please contact me (456-6466) or Ms. Dianne Levine (456-6429) who has been monitoring the benzene standard here.

Sincerely yours,

Barry P. Bosworth
Director

APPENDIX: ANALYSIS OF PROPOSED BENZENE STANDARD

Synopsis

The Council on Wage and Price Stability is concerned that the proposed standard does not reflect sufficient study of the costs and attendant health benefits of some very costly parts of the standard.[1] OSHA has not fully documented its case for adopting the proposed benzene exposure limit rather than a more *or* less stringent one. In addition, having decided upon the 1 ppm standard OSHA has not adequately considered the problem of designing a standard that will foster compliance with minimum cost. A standard that encourages this minimization of cost must be based on detailed estimates of the health risks in all sectors of the affected industries as well as the costs of reducing these risks by varying amounts in each workplace and using different means of controlling exposure. In other words the feasibility, cost and efficacy of alternative modes of achieving compliance with the 1 ppm standard must be analyzed. In so far as is possible the final standard should be flexible enough in the area of permissible means of compliance to enable each industry to adopt those alternatives that present the least cost burden while protecting workers to at least the mandated degree.

[2] Unfortunately the Economic Impact Analysis[2] does not contain the information that would enable OSHA to design such a standard. Cost estimates have not been broken down in sufficient detail to inform OSHA of the per capita cost of reducing exposure to benzene in different workplaces. Moreover the differing costs of this reduction when using varying control methods have not been investigated. It is in the work areas where the per person cost of exposure reduction is unusually high that alternative methods of obtaining the same worker protection should be considered. In particular, the use of respirators for exposures of limited duration (and totalling a minor share of the work week) should be considered.

The Council also strongly urges OSHA to consider the cost-saving advantages of adopting an "action level". The current proposal requires frequent and costly air monitoring and medical surveillance (as well as recordkeeping) in all workplaces where benzene is present. If an action level were adopted as it has been in other OSHA health standards, an initial determination of very low exposure levels (i.e. below the action level) would exempt firms from these requirements. When the work process is changed another measurement would be required to determine whether or not the action level is exceeded. This kind of approach would allow expenses to be cut where dangers are non-existent to workers without increasing the health risks attributable to benzene exposure. Moreover an action level approach would avoid the dangers of exempting entire industries from the regulation. For instance, the [3] proposal does not now cover wholesale bulk gasoline facilities or industries using liquids containing very little benzene yet these could conceivably expose workers to benzene at levels exceeding 1 ppm.

Thus the Council is concerned that a benzene standard be chosen that provides reasonable protection to workers and that once chosen, the standard be sufficiently flexible in terms of compliance so as to impose the least possible cost on society. In both these respects, but particularly the latter, we do not believe that OSHA has presented a proposal that is ready for adoption. We urge OSHA to expand its economic analysis of the benzene standard and to revise the proposal in light of the new information that can and should be developed within a fairly short period of time. In the meantime enforcement of the

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[1] This submission is made on behalf of the Council on Wage and Price Stability, an organization created by the Council on Wage and Price Stability Act (P.L. 93-387), within the Executive Office of the President. The authority of the Council to intervene in governmental rulemaking and ratemaking proceedings, conferred by Section 3(a) of the Act, has been delegated to the Director of the Council (see 40 *FR* 52882). The views expressed in this filing are not necessarily those of the individual members of the Council.

[2] *Economic Impact Statement: Benzene*, Vol. 1 and 2. Arthur D. Little, Inc., (Washington: OSHA May 1, 1977).

emergency temporary standard can serve to protect workers health from the dangers of benzene exposure.

Comments on the Proposal and the Economic Impact Analysis

The Council supports the goal of removing hazards to worker safety and health. Moreover, the Council appreciates the necessity of adopting a conservative or risk averse approach to worker exposure standards involving potential carcinogens and leukemia-causing agents. Yet these efforts to improve the work environment are not without cost, and OSHA is required by Section 6(b)(5) of the Occupational Safety and Health Act to consider the question of "feasibility" in developing its standards. Since OSHA is faced with a finite quantity of society's resources or maximum costs that can be allocated to worker safety and health in any industry, OSHA should pay serious attention to the develop- [4] ment of standards which will deliver the maximum increment of worker safety and/or health from every dollar spent on compliance. In other words, OSHA should search for the least expensive means of reducing the total risk of health impairment attributable to benzene exposure.

The Council notes that OSHA is proposing some flexibility in approaches to compliance with the proposed benzene standard; the proposal allows firms to select a mix, without restrictions, of work practice controls and engineering controls as long as those controls meet the 1 ppm average exposure and the 5 ppm ceiling exposure standard. We believe this is a significant improvement over the approach taken by OSHA in some previous occupational exposure standards.[1] By permitting the use of work practice controls, OSHA has taken a step forward

[1] See Arsenic (40 *FR* 3397), Lead 40 *FR* 45934), Sulfur Dioxide (40 *FR* 54520), Coke Oven (40 *FR* 33268) proposed standards. Under these proposed standards engineering controls must be adopted to reduce exposure levels to the lowest level achievable and then work practic control must be used to further reduce worker exposure. Finally respirators must be used if the above two control methods are not sufficient to reduce exposures to the permissible level.

in the direction of developing a standard that minimizes costs of compliance. However, the ceiling limit of 5 ppm for no more than one 15 minute period per day seriously limits the use of work practices to control worker exposure to benzene and, in effect, requires firms to install engineering controls. A slightly higher ceiling limit would make work practice controls more practicable. Alternatively, the use of personal protective devices in situations of sporadic exposure should be permitted in achieving compliance with the 1 ppm standard. In making these changes in the proposal OSHA would be allowing firms to choose the least cost means of complying with the standard.

[5] Additionally, there are certain inadequancies of the Economic Impact Analysis (EIA) which we would like to identify. Our comments note these inadequacies, first discussing the EIA of costs and then benefits. Finally we offer a few observations concerning regulatory alternatives.

Analysis of Costs

The Economic Impact Statement for the proposed benzene standard estimates that the total cost of compliance is about $267 million in initial capital costs, $124 million in additional first year operating costs, and $74 million in additional recurring operating costs in subsequent years.

Two significant problems exist with the cost estimates —both of which may lead to underestimates of the costs. First, a major sector of an industry and its costs of compliance have been excluded from the total compliance cost estimate. The language of the May 27, 1977 proposal, while clearly excluding "retail automotive service stations", does not exempt bulk storage facilities. A recent addendum to the proposed standard published in the *Federal Register* of June 24, 1977 (42 *FR* 32263), specifies that "the storage, transportation, distribution, dispensing or sale of gasoline as a fuel subsequent to the discharge from bulk terminals" will not be covered by the final permanent benzene standard. However the bulk plants or terminals themselves and the wholesale petro-

leum facilities are still included under the proposed standard. Arthur D. Little, Inc., notes that its estimates of the costs of compliance for bulk storage of gasoline and terminal storage of gasoline exclude facilities operated by independent wholesalers even though these facilities are covered by [6] the proposed standard.[1] As a result, the total costs of compliance have been severely underestimated. A separate section of the economic analysis estimates that the cost of bringing these facilities into compliance would be almost $4 billion or about $200,000 each. These costs are excluded from the total compliance cost estimates, presumably because "it is expected that secondary bulk plants would be phased out of gasoline service before incurring an investment of almost $200,000 each."[2] Even if these wholesalers are forced out of business or are merged into a major oil company, these functions will need to be performed. Thus, like facilities would still have to be brought into compliance at an estimated cost of $4 billion. The probability that secondary bulk plants would be forced out of business suggests that the regulation is *prima facie* infeasible at least as to that part of the industry and may well be infeasible as a whole.[3]

The second source of compliance costs that has not been considered in the analysis involves possible higher costs of substitute solvents and the costs of finding and introducing these solvents in tire manufacturing and in miscellaneous rubber products industries. The only costs of compliance considered in these industries are those of monitoring, medical surveillance, respirators, personal protective equipment, [7] training, recordkeeping, and

[1] *Economic Impact Statement, ibid.*, p. 1-8.

[2] *Economic Impact Statement, ibid.*, p. D-37.

[3] It is clearly a legal judgment as to whether a standard is "feasible" within the meaning of the OSH Act in specific factual circumstances. However, it is generally acknowledged that bankruptcy is a *prima facie* indication of economic infeasibility. Our position is that infeasibility as that term is normally used with regard to economic matters occurs at a point well prior to bankruptcy; a substantial number of authorities support that position.

signs. No capital costs are listed because of the presumption that substitutes will be found for benzene. A correct approach to costs of compliance necessitates inclusion of capital costs of engineering controls if feasible or a discussion of the cost, suitability and availability of substitutes for benzene in these production processes.

Analysis of Benefits

The Council is well aware that benzene has been shown to be a cause of leukemia. However the studies that have demonstrated this cause and effect relationship involved exposure levels that were many times higher than the 10 ppm of the currently existing standard. Over time there has been a substantial decrease in worker exposure levels so that now few if any workers are actually exposed above 10 ppm. American consumers as well as American workers are entitled to know what the benefits are of reducing the occupational exposure level for benzene from 10 ppm to 1 ppm.

While the Council in no way wishes to question the expert opinions of those scientists who have examined the data and concluded that benzene is a serious hazard to worker health,[1] we would expect [8] a more detailed analysis of the magnitude of the health risk in each industry and plant affected. The number of cases of leukemia that can be expected to occur in each plant as a result of current exposures to benzene can be calculated using data that are currently available. The Economic Impact Statement estimates that 191,000 workers are

[1] *NIOSH Criteria Documents for Benzene* revised August 1976. Andjelkovic, D., Taulber, J. and Symons, M., "Mortality Experience of a Cohort of Rubber Workers, 1964-1973," *Journal of Occupational Medicine;* 18, 6; p. 387-394 (1976); Infante, P. F., Rinsky, R. A., Wagner, J. K. and Young, R. J., *Leukemia Among Workers Exposed to Benzene,* NIOSH Progress Report, April 26, 1977; McMichael, A. J., Spirtas, M. S., Kupper, L. L., "An Epidemiologic Study of Mortality within a Cohort of Rubber Workers 1964-72," *Journal of Occupational Medicine;* 16, 7, p. 458-464 (1974); Monson, R. R., and Nakano, K. K., "Mortality Among Rubber Workers," *American Journal of Epidemiology* 103, p. 281-296 (1976); and Vigliani, E. C. and Forni, A., "Benzene and Leukemia," *Environmental Research 11,* 122-27 (1976).

now exposed to benzene at levels that exceed the proposed 1 ppm and it broadly discusses the nature of those exposures. The expected lifetime incidence rates of leukemia and the increased incidence rates revealed in the scientific studies [1] can be applied to the benzene-exposed population [2] to derive the number of expected excess cases attributable to that exposure. Varying assumptions about the dose-response relationship should be made to develop an estimate of cases of leukemia which would not occur if the proposed benzene standard is adopted. This last step is necessary because the levels of benzene to which the workers in the scientific studies were exposed were probably substantially higher than existing exposure levels in American industry. The study on which the estimate of a five-fold increase in leukemia incidence was based analyzed a population which experienced exposures from 1940 through the 1960's [3] when common exposure levels were up to 100 ppm (particularly in the 1940's) or up to ten times the current 10 ppm standard. Most of the 191,000 workers to be affected by the proposed benzene standard are exposed to benzene at levels that are currently substantially [9] below 10 ppm.[4]

While the Council does not contend that the above procedures will yield an accurate calculation of incremental benefits, they would provide a range of health benefit estimates that should be included in an economic analysis in order to aid OSHA in setting the final standard. These estimates of incremental benefits should also be developed for each industry covered by the proposed standard. Since current exposure levels in affected industries vary over the range of 0 ppm to 10 ppm and the number of workers exposed varies widely too, the incremental benefits of the proposed standard can be expected to differ between in-

[1] National Cancer Institute, *Third National Cancer Survey: Incidence Data* Monograph 41 (HEW-PHS-NIH: Maryland, March 1975), p. 116-117 and p. 450-451.

[2] *Economic Impact Statement: Benzene,* Chapter 4.

[3] These exposures began in 1940-1949.

[4] *Economic Impact Statement: Benzene,* Chapter 4.

dustries and workplaces. Such a breakdown of expected benefits, together with data on incremental costs of compliance, are necessary to analyze the cost of reducing risk in each industry and are essential in finding the least costly way of doing it.

Analysis of Alternatives

OSHA's economic impact analysis lacks any discussion of the costs and benefits of alternative standards or of alternative means of compliance with the 1 ppm standard.

It appears critical for OSHA to investigate both incremental costs and incremental benefits of more stringent standards as well as less restrictive standards. These estimates are necessary to determine whether a proposed standard should be made even more stringent or perhaps relaxed in some circumstances.

[10] It is even more important that OSHA consider more flexible ways of implementing the standard so that industries and workplaces with differing costs of implementation will be free to use the least cost means of reducing worker exposure. It is in this area that a detailed cost study is most useful to the policymaker since it will identify work areas where more flexibility in accepted means of compliance is warranted. Work areas with very few exposed workers and high costs for engineering controls might be permitted to achieve compliance by using a combination of means including respirators and work practices. These alternative means of compliance may reduce the problem of the $4 billion capital costs of compliance in the gasoline storage and distribution sector noted above.

The proposal does not state an "action level of exposure." [1] Monitoring, medical surveillance, and record-

[1] An "action level"—a concept employed in many other health regulations—is usually one-half the permissible exposure level. If the action level is reached in a workplace, air monitoring and medical surveillance must continue periodically. Otherwise they are not required until a work process has been changed. The purpose of an action level provision is to provide an extra margin of safety and to ensure that workers will not be exposed to dangerous concentrations of toxic substances. At the same time these measures may be avoided when exposures are very low.

keeping must be conducted in all workplaces where benzene is present no matter how small the quantity or the frequency of use. This entails considerable cost with probably little benefit. Therefore the Council urges OSHA to consider adoption of the "action level" approach for benzene. As in other proposed standards containing an action level, an initial determination of exposure levels would indicate whether or not the recordkeeping, air monitoring, and medical surveillance requirements of the standard must [11] be followed. The action level is usually one-half of the permissible level and exposures below it exempt the firm from the other requirements. Process changes involving the hazardous substance call for new exposure measurements.

As the proposal is now drafted, the requirements for periodic measurement, extensive recordkeeping, and quarterly medical examinations apply wherever benzene is present.[1] It would seem that these expenses can be avoided by the use of the action level approach without any reduction of benefits attributable to the standard. Such an approach would also cover all industries where liquids containing benzene are used but it would allow workplaces that use benzene rarely or indirectly and offer no risk of benzene exposure to employees to avoid most of the regulatory costs.

Another alternative that deserves consideration on the basis of costs and benefits is the adoption of a separate safety and health standard for laboratories where many different toxic substances are used. Most laboratories keep benzene on hand since it is a unique solvent that must occasionally be used. However, its use is very limited. The proposal subjects these labs to the extensive requirements of the standard. Even if their use of benzene is extensive, it may be beneficial to adopt an alternative approach under which laboratories would be excluded from this benzene standard and practically all other individual health standards. However, the use of all dangerous substances would be regulated under a single all-

[1] Exceptions exist in the sale, storage and distribution of gasoline and for liquids containing minute amounts of benzene.

inclusive rule that might better [12] take into account (and perhaps require) the unique procedures, equipment and personnel training of a laboratory.

Summary and Conclusion

The economic analysis submitted by OSHA appears to have done a reasonably adequate job of estimating the incremental aggregate costs of the proposed standard but it does not provide adequate estimates of the incremental benefits of reducing the permissible exposure level of benzene from 10 ppm to 1 ppm. Nor has it considered alternative exposure levels and implementation plans. Partly because of its lack of adequate benefits estimation and consideration of alternatives, the analysis has not been adequately integrated into proposal development. The suggested improvements in the analysis can be made in a short time and should help decisionmakers at this stage of rulemaking. The permanent standard should be delayed until this can be done. In the meantime the temporary standard can serve to protect worker health.

We urge OSHA to consider allowing greater use of respirators and work practice controls in areas where exposure is only intermittent and in general to permit the least cost (or most cost-effective) method of compliance to be used. We also urge OSHA to study the costs and benefits of adopting an action level to trigger the costly requirements involving medical surveillance, recordkeeping and monitoring. A separate toxic substance standard for laboratories, geared to their unique conditions, merits some consideration as well.

[Exhibit 115.A-9]

TESTIMONY OF

PROFESSOR RICHARD ZECKHAUSER

BEFORE THE

OCCUPATIONAL SAFETY AND

HEALTH ADMINISTRATION

July 11, 1977

Q. Please tell us your name and present position.

A. My name is Richard Zeckhauser. I am Professor of Political Economy in the Kennedy School of Government, Harvard University. I teach courses in the Law School, Kennedy School and Economics Department at Harvard.

Q. Do you have previous experience in the occupational safety and health field?

A. Yes. I recently completed a comprehensive overview of the Occupational Safety and Health Administration for the Senate Committee on Government Operations. The Senate Committee will be publishing that study later this summer.

Q. Are you an expert on the technological and medical aspects of occupational safety and health?

A. No, I am not.

Q. What is your area of expertise on this issue?

A. I am an economist and policy analyst. My major research involvement at the present time is regulatory issues. I have devoted particular attention to procedures designed to protect and promote human health. I have published a number of professional papers on the life valuation and life protection issue. Two recent publications include: "Where Now for Saving Lives?," with Donald Shepard, *Law and Contemporary Problems*, Fall 1976 and "Procedures for Valuing Lives," *Public Policy*, Vol. XXIII, No. 4, Fall 1975, 419-464. My resume and bibliography are appended to this testimony.

Q. In what way is economics relevant to this subject? Human health, after all, is not a commodity such as those economists usually study.

A. Economics as a discipline is directed to one subject: How should we [2] allocate scarce resources to achieving competing objectives? Virtually every policy field involves competing objectives and scarce resources. Where occupational safety and health is concerned, at the same time that we are attempting to conserve on the expenditure of resources, we are attempting to make the greatest possible contribution to human health.

As part of my testimony here today, I shall be pointing out that only by approaching these difficult policy ques-

tions in a systematic manner can we be assured of achieving the maximum gain in occupational safety and health for whatever level of resource expenditure that we make.

I agree strongly, I should point out, with the argument that human health is not a traditional commodity such as those normally traded on markets. The valuation of lives involves and reflects many of the most basic beliefs and institutions of our society. Given these characteristics, it should not be surprising that some of our decision and allocation mechanisms get tangled. These are the times when the organizing concepts of economics are likely to make their greatest contribution.

Q. Would you suggest that in formulating the proposed standard for benzene and the administrative procedures for implementing it that the Occupational Safety and Health Administration has gotten involved in such a tangle?

A. Yes, I do, though I would prefer to return to that set of issues later after we have had more chance to lay out what I, and what the overwhelming majority of the members of the economics and policy analysis professions, believe to be a sensible and sensitive approach to the problem of protecting human health and lives.

[3] Q. It is sometimes suggested that the economic approach leaves aside a number of considerations that may be important to society when it is involved with programs that save lives. In particular, the question may be raised whether the cost-benefit approach, wherein a price tag is attached to each life lost, has legitimacy in the eyes of decisionmakers and the public. What is your response?

A. First, I think it is important to understand the central lesson of economics is that we should make a conscientious effort to determine what proposed policies will cost us, and what they will achieve for us. The argument against this lesson would have to be that ignorance is better than knowledge. I believe that such an argument would be rejected by the participants on all sides in this hearing. The second lesson of economics is that we should attempt to get our preferences and priorities straight. In the area of health protection, I believe

that there would be little disagreement if we posed as one major objective the effort to achieve maximum health protection for whatever level of resource expenditure that we make. That is, if we are to spend say $5 billion additional dollars in 1980 for occupational health and safety, we should try to organize our programs so that that $5 billion dollars achieves the greatest gains possible. If one allocation would save 5,000 lives and another would save 10,000 lives, then we should prefer the second allocation. (In actual policy making contexts, of course, the problem is more complicated. In particular, it is usually difficult to predict accurately how many individuals will be saved by any particular intervention.)

If we fail to pay careful attention to our priorities in these matters, [4] then we will find that we have achieved less for health and safety than we could have, given our levels of resource expenditure.

I should be explicit. I am not arguing that a cost-benefit approach be employed in formulating policy on occupational safety and health. Such an approach would require that a dollar price tag be attached to a life saved. The value of the lives saved would then be weighed against the resources invested to find the program that offered the highest net value. The major objection to this approach is that there is simply no widely accepted procedure for determining the value of lives in contexts such as these.

Fortunately, there is an alternative approach, called cost-effectiveness analysis, that enables us to establish priorities in programs for saving lives. The guiding principle of cost-effectiveness analysis is that for whatever level of resource expenditure we are undertaking, we should attempt to gain the maximum possible level of effectiveness. The cost-effectiveness technique has been applied in a range of areas where outputs cannot readily be translated into dollar terms, from defense to health policy. The criterion for effectiveness in the occupational health area would be health or lives preserved.

Cost-effectiveness operates by ordering potential policies, starting with those that offer the greatest health gain per dollar expended. These policies are then adopted in

rank order until a particular level of resource expenditure is reached. The level of expenditure may be determined through a preassigned total, perhaps a budget, or it can be the result of some political process. When projects are adopted in this fashion, the highest level of effectiveness will be achieved for whatever level of [5] resources is expended. A critical characteristic of the outcome will be that every project that is adopted will yield a higher level of effectiveness per dollar than any project that is not adopted.

I should like to digress for a moment to make a slightly technical, but highly important point. In conducting cost-effectiveness analysis of programs, or indeed an analysis of any type of program, it is important to determine not only how much is achieved on average for a particular level of expenditure, but how much is achieved at the margin. Let us assume that a proposed program could save an expected 100 lives for an expenditure of $20 million, or $200,000 per life saved. That program might look very attractive in comparison to an alternative that could save lives for $500,000 apiece. But we should also examine the benefits of the first program at lower levels of expenditure. Frequently it is the case that the last measure of protection provided is extremely expensive. For example, in their recent book *Pollution, Prices, and Public Policy* (Brookings Institution, 1975, p. 21), Allen Kneese and Charles Schultze, presently Chairman of the Council of Economic Advisers, note that with pollution control "going from, say, 97 percent to 99 percent removal may cost as much as the entire effort of going from zero to 97 percent." Let us suppose that if the hypothetical program introduced above is cut from $20 million to $10 million, by eliminating its least cost-effective components, the number of expected lives saved will be reduced only from 100 to 95. In that case the marginal cost of saving the last five lives would be $2 million per life. Thus the program should not be operated at the $20 million level until all opportunities to save lives for $1 million each have been exhausted.

[6] This lesson is easily overlooked when occupational health standards are enacted. We might look at a standard that reduces exposure by an amount X at an expenditure of $100 million. The gain may seem worth it. But the gain at the margin may be rather minimal. What if we could achieve a reduction of 99% of X for an expenditure of merely $50 million? Well, that last small reduction in exposure would be costing a very great deal. We still might choose to make the expenditure, but we also might not. The important point is that we should have the marginal effectiveness information available so that we could make an intelligent choice.

Cost-effectiveness analysis starts with a recognition that any government policies directed towards lifesaving involve tradeoffs between resource costs and lives and health. Several years ago, for example, the maximum speed limit was lowered to 55 mph, primarily to conserve fuel. It is generally agreed that the reduced limit also saved several thousand lives. It is clear that we could save even more lives if the speed limit were lowered again, or if the current limit were enforced more strictly. Yet we do not take these steps, I would suggest, because we recognize at least implicitly that there must be a balance between safer highways and the cost of slower speeds, which are measured both in terms of dollars spent on transportation and the time and convenience of automobile travelers. If bodily well-being were the only concern, we would bring all traffic to a halt.

We must recognize as well that any standard that is set for any health hazard implicitly reflects a tradeoff. One thrust of my testimony, and a central tenet of the analytic approach to livesaving, is that it is best to know what that tradeoff might be. As the complete elimination of [7] traffic could eliminate auto fatalities, so too closing down a number of critical industries in the United States could prevent any worker exposure to benzene. We do not wish to pay the shutdown price in either area, so we set the standards to permit some activity, recognizing full well that some threats to health continue. There is no positive level of exposure that we can be deemed 100 percent safe, just as there is no positive speed which eliminates all probability of accident. The level of risk

we accept should reflect the degree of risk we wish to take.

The second principle of cost-effectiveness analysis is that when attempting to accomplish some end such as protecting human health, we should direct economic resources where they accomplish the most. If the expenditure of an additional $1,000,000 would save five lives on the highway, but the same expenditure on plant safety would only save one life, then if we chose the plant safety expenditure over the highway expenditure, we would in effect be sacrificing four lives. The purpose of cost-effectiveness analysis is not to tell us what the tradeoff rate should be between dollars and lives or health, but rather to alert us to the need to rationalize decisions across areas where lives are being saved. If we are to rationalize in this way, we should start by seeing what health accomplishments can be achieved for various levels of expenditure in different areas. Frequently, decisionmakers or governmental agencies concerned with one area will not have responsibility for another. In those circumstances, they may be unable to achieve full consistency of tradeoff rates, that responsibility perhaps belonging to higher level decisionmakers. Still, they would retain responsibility for consistency, hence achievement of maximum health benefits, in their own areas. In the context of the current hearings, this would suggest that though OSHA may with some justification suggest that it cannot be responsible for the consistency of [8] its decisions with those of the Nuclear Regulatory Commission or the National Highway Traffic Safety Administration, it should make every attempt to be consistent across the broad sweep of problems encompassed by occupational health and safety. (The President, OMB and Congress, among others should keep an eye on consistency across agencies.) This principle also applies within the context of a particular standard. Ideally standards should recognize variations in costs across different industries, across firms within the same industry, and even across job categories within different plants.

Q. It is clear that you believe that analysis can play a critical role in assembling information about and making predictions about the consequences of alternative government policies. Could you comment on the possible benefits of more accurate predictions?

A. Yes. I would be glad to. Let me start by remarking on the type of conflict signified by this hearing. It is one of a number of basic debates over how the government should go about promoting health and protecting our lives. Some of these debates may reflect conflicts over values. But I think that they are likely to be in the minority. If we could really make accurate predictions of the consequences of alternative lifesaving and health promoting policies, in terms of both resources and physical well-being, much conflict over those policies would be reduced. The importance of improved prediction is that it helps us resolve debates that can be resolved, in contrast to debates over value questions.

Q. What type of debate do you think is represented by this hearing procedure?

A. Undoubtedly there are some disagreements on value questions. In other instances there may be straightforward struggles over who should benefit in what way and at whose expense. But the substance of the debate, quite clearly, should be over the benefits and costs of various possible standards, including the present permanent standard, the proposed standard, and a [9] variety of alternatives in between. If information of this sort could be presented to this hearing, there would undoubtedly be much wider agreement as to how we should spend resources in the most effective manner to protect workers against the adverse health effects of benzene exposure. This information would consist of answers to such questions as: What health benefits can be expected to be secured from giving medical exams to a particular class of workers four times a year rather than once a year, assuming that spot checks on a small fraction of workers show no unexpected effects? Or what would be the consequence of information loss if expenditures for monitoring programs for benzene exposure were cut by 30 percent below or raised by 30 percent above those in the proposed permanent standard?

Q. You have suggested that one aspect of the predictive effort should be to compute economic costs. What are the economic costs associated with a standard?

A. They are simply the sum total of what all parties have to spend to meet and enforce the standard. Though most of the spending will undoubtedly be undertaken by private companies, the burdens will be shared by consumers, workers and taxpayers at large. If a private corporation is in a 50 percent marginal tax bracket, for example, one half of any reduction in profits due to expenditures entailed by regulations will be borne directly by the taxpaying public as a whole. A further fraction would be borne, or course, given reduced taxes on earnings eventually going to shareholders in the form of dividends or capital gains. Of course, much if not most, of the expenditure will not come out of profits. Some will come out of the wages of workers. More will be passed on in the form of higher prices, in general the less elastic is the demand for the product. For example, since the price elasticity for gasoline is low, additional costs in gasoline production will be mostly absorbed through higher prices.

[10] The economic costs we are talking about represent real resources that could be devoted to other purposes in society. For example, in computing the economic costs of the benzene standard, we should recognize that doctors administering tests for benzene exposure to workers will not be available to deliver other medical services. The workers and machines producing monitoring equipment will be taken away from the production of other equipment that might have been used either to save lives, or to serve any other purpose of society.

Q. But it is well-known that most of the industries affected by this standard are composed of large firms that are profitable. Few firms will close down as the result of this standard. Does that imply that the economic cost is in some way contained?

A. No, it does not. We are still requiring the industries to expend resources that could be used to other purposes. When a company shuts down, there may be additional expenses as resources are shifted to new uses.

These "transition costs" are economic costs over and above those I mentioned earlier, which involve diverting resources from other productive uses. The dollar value of these diverted resources tell us what could have been provided to society if the standard had not been promulgated.

To sum up, there are two important attributes of any proposed standard. They are the health benefits that it can be expected to achieve and the economic costs it can be expected to impose. Thoughtful policy choice would require that careful attempts be made to predict the values of both sets of attributes.

Q. What important predictive information is contained in the Arthur D. Little report that provides an assessment of the proposed permanent standard for benzene exposure? What predictions that should have been made are not contained, and how important are the omitted areas of prediction?

[11] A. First, let me note that, lacking detailed knowledge of the industries and production processes affected by the proposed standard, I have not attempted to evaluate the accuracy of the cost estimates derived by OSHA's contractor. Any such prospective cost estimates, especially when they cut across several different industries, will, of course, be subject to a wide margin of error. Other witnesses, I am sure, are far better qualified to comment on the validity of specific assumptions made about the compliance activities required and their costs.

It is clear, however, that the efforts of OSHA and its contractor, the Arthur D. Little Company, to predict the benefits of the proposed standard have been totally inadequate. It is somewhat startling to read the ADL report—which comprises more than one hundred pages, with an additional two hundred pages of appendices—and discover that the section assessing possible benefits is only eight pages long, three of which are simply a list of references. The studies cited on the effects of benzene exposure are summarized only cursorily. Moreover, the majority of those studies were of workers exposed to benzene at levels far in excess of either the current or the proposed standard, and thus are of little relevance in determining the incremental benefits of the tighter exposure limit.

In discussing the benefits of the proposed standard, the ADL report refers rather vaguely to "reductions in leukemia potential, blood abnormalities, and general occupational morbidity . . . a better informed workforce . . . [and] . . . an increase in the body of knowledge related to all facilities utilizing benzene . . ." (p. 3-5). Neither the ADL report nor OSHA's discussion in the *Federal Register* make any attempt to quantify the health benefits of moving from the present standard to the proposed one. Let me stress again that by "quantify" I do not mean that the potential benefits need or even [12] should be expressed in terms of dollars. Rather, I mean that OSHA has provided no estimates of the number of lives to be saved or cases of illness to be avoided by the imposition of this standard. While I appreciate the fact that the limited data available make it impossible, as the ADL study suggests (p. 3-5), to specify "benzene's precise dose-response relationship," it is also impossible to evaluate the standard in any meaningful way without some estimate, however crude, of its benefits. Even if such an estimate could not be refined beyond a broad range of possible effects, it would be of immense value. From the documents I have seen, we have no idea whether the proposed standard would save no lives, ten lives, or 1000 lives for an annual expenditure of more than $100 million. At the very least, OSHA should present a range of estimates of the health losses due to current levels of exposure to benzene. With such estimates it would be possible to place an upper bound on the incremental gains of the proposed standard, as OSHA admits that it will not eliminate all health effects.

Q. What sort of analytic capability exists within OSHA that would have enabled the agency to make good use of predictions had they been provided?

A. Unfortunately, OSHA has made little effort in the policy analysis area. This has not been a priority of the agency in the past, and although a small policy analysis operation was begun in 1976, it has hardly achieved a central role within the agency. In the review of OSHA that Albert Nichols and I conducted for the Senate Committee on Government Operations, we concluded that:

"OSHA should establish as a top priority the development of a policy analysis capability that would enable the Agency to formulate concrete objectives, detail performance on those objectives, evaluate alternative approaches to governmental promotion of health and safety, and develop long run plans for OSHA." Until a strong policy analysis staff is put [13] in place, it seems highly unlikely that OSHA will be able to make use of either the type of analysis that Arthur D. Little prepared in assessing this standard, or the type of analysis that I have suggested should have been prepared.

Q. How could these predictions of the type you request deal with the fact that our scientific understanding of these issues is not complete, our data base is limited, and we do not really know from experience what benefits can be expected?

A. Your question merely reflects the facts that we are making a regulatory decision under conditions of great uncertainty. That is frequently the state of affairs. The more significant the uncertainties, usually, the greater are the benefits for some sustained study of the problem. If initial predictions of health benefits range, say, over two orders of magnitude, several months of investigation may narrow the predictions to within a factor of ten. Extreme narrowing of this sort may dramatically change both the form and severity of the regulatory intervention that we wish to employ in a particular case.

I should point out that there is the academic discipline of decision analysis that has been developed to deal with situations of considerable uncertainty. There are a number of primary lessons drawn from that discipline that would seem to be relevant to any attempt to set standards and procedures relating to benzene exposure. Let me cite three. 1) Make careful attempts to estimate the values of critical variables, specifying a range of uncertainty when appropriate. 2) Make conscientious efforts to estimate the value that new information would bring in terms of an improved decision; develop, assemble, and process information when its expected value exceeds the cost of producing it. 3) Where uncertainties persist, employ a sequential strategy, where future actions will be

[14] influenced by information gained along the way. There is no evidence that any of these lessons has been considered, much less applied, in formulating the proposed permanent standard for benzene exposure.

Q. There are many specific aspects of the proposed permanent standard relating to requirements across industries and job categories, the role of personal protective equipment, exposure measurements, medical test requirements, and the like. Can you comment on the overall structure of this approach?

A. Let me deal first with the question of variations across industries and job categories. The principle of cost-effectiveness states that the marginal cost of achieving a given increment of protection should be constant across industries and job categories. If it is not, we could achieve greater protection at the same cost by relaxing the standard where marginal costs are high and tightening it where they are low. OSHA has taken some cognizance of this principle by exempting certain types of firms, specifically those using benzene only at very low concentrations and those distributing and selling gasoline at the retail level. It has not, however, analyzed differences in marginal costs across the affected industries and across different job categories within each industry.

The proposed standard continues OSHA's general policy of opposing the use of personal protective equipment, in this case respirators, except in certain extreme cases. OSHA's primary argument is that respirators are not always properly fitted and often are not used by workers. However, in many instances it is likely that respirators offer a relatively low-cost alternative to engineering controls and should be permitted, even if engineering controls are "feasible" in a purely technical sense. Moreover, engineering and work practice controls hardly offer foolproof protection. Controls may be installed but not used or maintained properly. Workers may not obey the work practice rules set up by employers. Firms [15] should be permitted maximum flexibility in meeting whatever exposure limit is set. If firms choose to use respirators and workers find them uncomfortable or inconvenient, then certainly it would be appropriate for labor and

management to negotiate over the mix of engineering controls, work practice rules, and respirators used to meet the exposure limit.

On the issue of exposure measurements and medical test requirements, I am not qualified to comment on the technical aspects, such as what tests should be used, or what the appropriate interval is between tests. However, I find it rather remarkable that the costs of medical surveillance and exposure measurement each make up one third of the estimated first-year costs of compliance. Most of these costs will be incurred in workplaces where workers even now are not exposed to benzene at levels in excess of 1 ppm. It strikes me as being highly improbable that frequent medical surveillance is as necessary in low-exposure workplaces as in those above the limit. Reducing the frequency of testing could effect large savings, quite possibly at little or no loss in worker protection. The same may be said of exposure measurements as well, although OSHA has provided for less frequent measurements in workplaces found to be below 1 ppm. Given the very high costs of both surveillance and exposure measurements, considerably more analysis needs to be done on the question of how often different types of workers need to be tested and their exposures measured.

Q. What is your summary view of the proposed permanent standard on exposure to benzene and the analysis that was conducted by Arthur D. Little to support it?

A. First, it seems evident that no underlying principle was employed to establish the standard. I have suggested that cost-effectiveness analysis [16] does provide such a principle. It requires quite simply that we make our expenditures on occupational safety and health where they can be seen to yield the greatest benefit.

The analysis in support of the standard was highly inadequate in that it made virtually no attempt to measure the health benefits that the standard would produce. Obviously, there was no attempt to compute marginal benefits and costs associated with alternative standards. Those marginal quantities are the ones that should be focused upon in making any policy decision.

The form of the standard and the particular testing, evaluation, and monitoring procedures it requires suggests that little attempt has been made to limit resource expenditures where they can be expected to yield little health benefit, if any. Even the simple principles of sampling theory and elementary statistics seem to have been left aside in the design of the standard.

Q. What action would you recommend be taken on the permanent standard?

A. It would be inappropriate to take any action—be it adopt, reject, or modify—without the information that would be required to make a sensible decision. I would strongly urge that analyses be commissioned to compute the marginal benefits and marginal costs of the major aspects of the standard. Given such information intelligent decision making can proceed. In the absence of such information, no decision could reflect more than an emotional or political response to an uncharted situation. Much is at stake in the establishment of a permanent standard on benzene exposure. Intelligent decision making should be given a chance.

[Exhibit 115.C-1]

TESTIMONY OF DR. HOWARD I. MAIBACH

BEFORE THE

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION

July 11, 1977

My name is Howard Maibach, M.D. I received my A.B. in 1950 and my M.D. in 1955 at Tulane University, New Orleans, Louisiana. My internship at the William Beaumont Army Hospital, El Paso, Texas (1955-56) was followed by two years of military service—initially at Walter Reed Army Hospital, Washington, D.C. and then at the 42nd Field Hospital in Verdum, France, where I was in charge of neurology, psychiatry and dermatology. Completing military service I matriculated at the University of Pennsylvania in Philadelphia, Pennsylvania for clinical and research training in dermatology from 1958 through November 1961. I joined the staff of the University of California Medical Center, San Francisco, California as an Assistant Professor in 1961; I remained and am presently Professor of Dermatology.

My research interests concern the biology of the skin and, most specifically in regard to this testimony, the effects of the chemical environment on the skin. I authored or co-authored approximately 300 papers and edited 5 books.

My curriculum vitae and bibliography are attached (Maibach Exhibit 1).

This bibliography covers a broad range of cutaneaus research; several specifically concerning the effects of chemicals on the skin. Most directly, publications from 1965 to the present document the penetration of chemicals through the skins of animals and man, and the relevance of animal models to man.

[2] I reviewed the information supplied by counsel for API and NPRA that has been cited by the Occupational Safety and Health Administration ("OSHA") proposed prohibition of skin contact with benzene to determine whether it provides an adequate basis for rulemaking in this area. These include: Hanke, J. T., Dutkiewica, and I. Piotrawski: (The absorption of benzene through the skin in men.) Med. Pracy 12:413-26, 1961 (OSHA Doc. No. 69); Cesaro, A. N.: (Is absorption of benzene through the skin possible?) Med. Savoro 37:151-156, 1946 (Ital.) (OSHA Doc. 47); and Dutkiewicz, T., H. Tyras: A study

of the skin absorption of ethylbenzene in man. Br. J. Indust. Med. 24:330-32, 1967 (OSHA Doc. 123).

My comments relate solely to the state or the science and art of quantitating percutaneous penetration. I have not reviewed the entire issue of benzene toxicity as this relates to prohibition of use or level setting.

In discussing the relevance of percutaneous penetration to a biological effect in either animal or man, the observed biological or clinical effect involves how much of the material penetrates the skin and what is the biological effect of that material when it enters the body. Chemicals severely toxic when injected into animals in small amounts may be safe for man if this does not penetrate. Conversely, chemicals with moderate animal toxicity can produce toxicity in man if large amounts [3] penetrate. Thus, in extrapolations of what is likely to be observed in man, one needs the kinetics and total penetration and the biological potential of that penetrant. The question at hand is how much benzene is absorbed through the skin? The most pertinent data at the present is: Hanke, Dutkiewicz and Piotrowski, Institute of Industrial Toxicology of the Institute of Labor Health, Lodz, Poland, Absorption of Benzene Through the Skin (Med. Pracy 12:413-26, 1961). These authors summarized the literature to 1961 and added experimental data.

The first reference is Lazarev, Brussiolovskay and Larov (1931), who conducted tests on rabbits and mice. Contact with liquid benzene was accomplished by immersion of the animal's ear or paw in the liquid benzene for several hours. We have no experimental data permitting extrapolation of this type of prolonged immersion experimentation to casual contact in man, nor do we know how to extrapolate data from the rabbit or mouse ear or paw to man.

It is known through studies of several materials, not including benzene, that rabbit skin is many-fold more permeable than human skin. (Bartek, M., LaBudde J. and Maibach, H.): Animal model for percutaneous absorption, Chapter 13 in Animal Models in Dermatology, Churchill Livingstone, London, 1975 (Maibach, H. ed.) (Maibach Exhibit 2).

Furthermore, any extrapolation from these animals' ears or paws being immersed for many hours to man must be made with [4] great caution. Lazarev *et al.* determined that the absorption rate was approximately 3 milligrams per square centimeter per hour. Although this could hold true for man, we do not at the present have studies comparing the two species to allow us to make this extrapolation.

In the Lazarev study the skin was "mummified" by benzene exposure. Presumably this means markedly damaged skin not comparable to that of the normal worker dealing with benzene.

Cesaro (Med. Lavoro 37:151-6, 1946) placed adult males nude in a metal tank for 20-30 minutes. Their skin was exposed to unspecified amounts of benzene vapor and liquid. Utilizing an inorganic sulfate—total sulfate method, he examined the subjects urine to determine if penetration occurred. He sought benzene in their expired air with an apparatus consisting of a mechanism to bubble the breath through a formalin solution in concentrated sulfuric acid. Benzene, if present would produce a brown color.

In neither experimental circumstance did he observe data suggestive of percutaneous penetration.

This negative data must be interpreted with caution; neither assay had sufficient control data to permit an estimate of sensitivity; i.e., what is the minimum detectable level?

Teisinger and Fiserova-Bergerova (1955) quantitated the percutaneous penetration of benzene by measuring the amount of phenol in the urine of man. Hanke et al. believed that this was [5] a sensitive method and, thus, utilized it in their studies. Comments as to its sensitivity follow.

In the Hanke et al. study, benzene (0.02 ml) was applied by microsyringe to a watch crystal pressed to the forearm with an elastic. "The glass is placed under a funnel having a slightly larger diameter which, with the aid of a short elastic connecting piece, [was] connected to a water suction pump through a rinsing machine with a porous glass containing 20 ml of nitrating mixture

(10% ammonium nitrate in concentrated sulfuric acid) as an absorbing solution."

It is not clear if the watch glass was used as an occlusive dressing. If it was we believe that penetration would be ten-fold higher due to occlusion (when comparing this to the usual nonocclusive application of benzene to human skin). For most studies published to date, occlusion increases penetration approximately 10-fold. Feldmann and Maibach, published studies, and Feldmann and Maibach, unpublished studies (Maibach Exhibit 3). This occlusion enhancement has been documented for hydrocortisone, testocterone and several pesticides. Although it is possible that some workers do occlude their skin when contacting benzene, these figures resulting from occlusion must be separated from those without occlusion.

In addition to measuring the urinary excretion of phenol, Hanke et al. trapped benzene coming through into the funnel.

They performed 52 tests of the concentration of phenol in [6] urine, finding an average of 7.2 milligrams per liter of phenol in urine in subjects not known to be exposed to benzene. This was the baseline observation to which their subsequent data relates. Expressed in milligrams per hour this is 0.2 percent per hour.

They exposed volunteers' forearms. They state that "a plate with benzene saturated cotton was placed on the forearm" with a dose of about 0.06 grams per centimeter square. "This plate was insulated with the aid of cellophane affixed to the forearm with adhesive tape. The contact area was 35 to 45 centimeters square and the contact time 1.25 to 2 hours." This suggests this exposure was occlusive; the importance of this relates to the previous comment as to the effect of occlusion on percutaneous penetration in man (increasing this by approximately ten-fold). Note also the prolonged contact time (1.25 to 2 hours), which is longer than casual contact.

"The urine samples were taken for an entire day, every 1 to 3 hours, and less often at night." It appears that they did not have a complete urine collection.

The data for the five subjects was reported as the maximum concentration in milligrams per liter and the

rate of excretion in milligrams per hour. For example, the maximum concentration, which they termed physiologic excretion—for non-exposed subjects, was 16.0 mg/1 while the level for exposed subjects were as follows: 15.8, 17.0, 28.3, 22.1 and 16.9. Thus, of the five subjects, 2 were above baseline and 3 were essentially similar to baseline.

[7] Physiologic (baseline) excretion was listed as 0.57 milligrams per hour whereas excretion in exposed persons was 0.79, 1.7, 0.96, 1.9 and 0.75. Again, two of the subjects were significantly higher than the remainder.

Unfortunately, they do not have baseline data on each subject so that each subject could act as his own control; this would help determine whether these were subjects who had been exposed to any phenolic material that would be excreted as phenol. The authors do not appear to eliminate the possibility that these two subjects represented contamination from another source.

There is inadequate kinetic data present that would allow us to ascertain that, after exposure, levels went up and then decreased in a meaningful way. The data given in Figure 5 documents the extensive variation of phenol excretion in a non-exposed subject.

Making these calculations, they concluded that, under these particular methods of exposure and using this method of determining benzene penetration (phenol in urine), the average rate of absorption was 0.24 milligrams per centimeter per hour. They cautioned that "in view of the number of assumptions made in the course of calculation, this value should be taken only as a reference value."

The authors caution "it should be noted that the results pertaining to the rate of absorption of liquid benzene through the skin refers to the extreme case, where the skin of the exposed [8] individual is *completely damped by benzene at the point of contact;* these are thus maximum values." If this means that the watch glass was in fact occlusive these factors are at least ten-fold more than would be seen in casual exposure (without occlusion or soaking).

Since benzene is highly volatile, if the rate of volatility was greater than the rate of absorption, this would greatly alter the amount penetrating when there was no occlusion present. In this instance, the ten-fold enhancement with occlusion may be an underestimate of the total enhancement factor.

Hanke placed three nude subjects with both water hydrated skin in a chamber exposing them to benzene vapors at 1.0 mg/liter (air temp, 25°C and humidity, 35%). Utilizing urinary phenol excretion as an index of penetration, no increase was noted, after 1.5 hours exposure. With seven hour exposure, they noticed an increase of phenol excretion of 2.7 and 4.2 respectively. They state: "If we consider that at the same concentration of benzene in the air (1 mg/liter) and pulmonary ventilation of about 3 m^3/7 hours, the amount of absorption through the lungs would be about 1500 mg."

Comment:

In summary, there are many incomplete facts in the available data making it extremely difficult to extrapolate to make any relevant decision for man in 1977 based on knowledge of the actual amount of benzene absorbed from normal skin in casual contact. [9] To improve the situation we need the following: (1) percutaneous penetration data performed with a technique that is likely to ascertain if the material absorbed is or is not benzene or one of its metabolites. At the present, the most effective way to do this would be to use carbon 14 labeled benzene.

To verify that absorbed benzene or metabolite can be monitored, a tracer amount of benzene should be injected into the animal (or man) to verify that completeness of recovery has been obtained in either urine or feces. If the material is expired in air, or if the material is stored in a body site, the errors utilizing urinary excretion may be considerable. If the entire parenteral dose can be accounted for by this process, it can be assumed that the estimates of absorption through skin are likely to be accurate.

(2) It is important to determine what the half life of excretion is once the material is absorbed. This will help determine who long urine and/or stool should be studied after a single dose. This calculation can be made simply on the basis of the parenteral control.

(3) Hanke et al. assume that the fate of benzene from skin exposure involves a given percentage being metabolized to phenol. This is probably the case, but additional experiments should be sought to document this. Until this is documented, one must *not* assume that the fate of benzene via the lungs is the same as the fate of benzene via skin contact. There are [10] several examples in which the metabolism from parenteral and cutaneous exposure has been compared and in which there has been significant differences between the two. E.g., corticosteroids (Mavis, Greaves, J. Invest. Derm.) (Maibach Exhibit 4).

(4) We should know the effect of a variety of concentrations on the skin. For some compounds there is a linear dose relationship: the more it is applied, the more it goes through. Ref. Wester, R. and Maibach, H., J. Invest. Derm. 1976. This does not hold for all chemicals. The only way to know this for benzene is to do the experiment.

(5) We do not know if multiple applications will produce more penetration than single applications. It is ordinarily assumed that each time you apply the material, more of it is being absorbed: recent studies with two chemicals show that this is not always the case. Wester, Noonan and Maibach, Frequency of Application of Percutaneous Absorption of Hydrocortisone, Archives Derm. 113:620, May 1977 (Maibach Exhibit 5).

(6) We should know the effect of splashing of the material on skin compared to soaking on skin. With splashing, it is possible that the material may evaporate too rapidly to penetrate; this might be different than that absorbed from a dressing or in an occlusive cutaneous exposure such as noted in these studies.

Obtaining this data should be relatively straightforward with the availability of carbon 14 labeled benzene. If it is deemed necessary to do this first in an animal, the

rhesus [11] monkey is the animal that has the greatest amount of background data comparing permeability to that of man. The comparative studies are summarized by Wester, R. and Maibach, H.: Penetration in Animal & Man in Cutaneous Toxicity, 1977 (Drill, V. ed.) (Maibach Exhibit 6).

The amount of time required to obtain additional data would be six to eight weeks; an extensive profile of penetration could be obtained in 12 to 24 weeks. Similar studies could be safely done in man because the chemical and radiologic exposures are extremely small.

[Exhibit 149.B]

DIRECT TESTIMONY OF RICHARD WILSON

Experience

1. My name is Richard Wilson. I live at 15 Bracebridge Road, Newton Centre, Massachusetts and I work as a Professor of Physics at Harvard University. I obtained my B.A. in Physics at Oxford in 1946 and my M.A. and D. Phil. in 1949. I have done research and taught at several institutions since then.

2. My principal research has been in nuclear and elementary particle physics.

3. In the last six (6) years, I have become interested in the environmental and public health hazards of energy systems. I have taught a course in this at Harvard and am acting Director of the Energy and Environment Policy Center at Harvard. This has led to my making comparative analyses of many hazards in life.

4. Recently I have been a consultant on reactor safety to the State of Maine, and also a consultant to the Energy Research and Development Administration, the Nuclear Regulatory Commission. I am studying safety of liquified natural gas facilities for the General Accounting Office.

5. I have worked with radiation all my professional life and have become aware of the risks and dangers of radiation—from x-rays as well as from radioactive materials. I am Chairman of an interfaculty committee at Harvard which runs the Harvard University cyclotron, built originally for physics research and with which I did nuclear physics experiments, but now used for medical treatment of various tumors—both proliferating and non-proliferating. In this capacity I work with the head of the radiation medicine department at Massachusetts General Hospital (who is a member of the committee) and some of his staff. My knowledge of the effects of low levels of radiation is accepted by them, and I have lectured to the interns and residents on this subject. Thus, I am well aware professionally of the problems of

cancer. I am also well aware on a personal basis since my stepmother died of cancer 15 years ago and my father died two months ago—both probably attributable to tobacco smoking.

6. I have twice testified on safety at the Joint Committee on Atomic Energy of the U.S. Congress; I have testified on risk/benefit analysis at a Subcommittee of the Committee of Science & Astronautics of the U.S. House of Representatives; I was asked by the Food & Drug Administration to comment on the proposed saccharin ban and have testified at an FDA hearing. I have lectured on risk/benefit analysis at energy symposia, an American Chemical Society meeting, and at a special Risk/Benefit Conference at Asiloma, California.

Introduction

7. I wish to testify about the level of risk that may conservatively be associated with the use of benzene in its occupational setting and, hopefully, put this risk into some perspective with a number of other risks that society has prudently chosen to ignore or accept. I have not personally done the experimental work which produces the numbers which go into the analysis, but I have reviewed the documents presented, and others to which I will refer. I have paid particular attention, of course, to those areas where the Occupational Safety and Health Administration (OSHA) and the Manufacturing Chemists Association (MCA) appear to disagree. I will outline the logic of this analysis, and try to highlight for you those places where assumptions are made. In such analysis there are places where good data do not exist, and we hope never will exist (we have not deliberately given one million American workers large doses of benzene to find their sensitivity directly); therefore, the evidence must of necessity be imprecise. Nonetheless, there is a logical procedure, which can demonstrate with conservative assumptions that an average level of benzene in the workplace of 10 ppm is much more acceptable than many other actions.

8. I wish to make it clear that *before* agreeing to testify, I satisfied myself that the benefits attributable to the manufacture of benzene with a 10 ppm level outweigh the potential risks associated therewith. The purpose of this testimony is to present an estimate of the occupational risk in terms which permit a comparison to other risks which society regards as insignificant.

[Figure 1 Omitted in Printing]

The Problem

9. The scourge of cancer afflicts one quarter of all Americans in their lifetime, and 18% of Americans eventually die from the disease. Massive efforts have been made to discover the causes of cancer and to effect a cure. About $25,000 per patient is spent trying to cure cancer.

10. In the last year, there have been several reassessments of the direction of this attack. For example, the prestigious public interest lobbying organization, the Federation of American Scientists, has summarized a part of the issue in a recent public interest report (May 1976). In the last 15 years, there has been very little improvement in the cure rate for cancer. This is shown dramatically in Figure 1 where the survival rate has been only slightly improved.

11. The trends in cancer mortality rates are shown in Figure 2. These are adjusted by age. This is necessary, because cancer afflicts old people more than young people, and as other causes of death are removed from our society, a larger proportion will die of cancer. This age adjustment removes much of the pragmatic rise in cancer over the last few years. But for some cancers, mortality *has* dramatically increased.

[Figure 2 Omitted in Printing]

12. Attempts to find a universal cancer virus which causes cancer have so far failed. If a virus were found, a vaccine against cancer would be possible. Therefore, a vaccine against cancer does not seem likely in the near future. Accordingly, society is left with two immediate choices—accept cancer and try to cure it by surgery,

radiation or chemotherapy, or try to remove the causes of cancer.

13. It has been widely stated that between 80% and 90% of all cancers are of environmental origin. The word environment must be used in its broadest sense. Although the evidence either way is not definitive, most cancers do not seem to be caused by genetic defects passed on by the previous generation or by a contagious virus. If this is true, they can only be caused by man's environment: the air we breathe, the food we eat, the tobacco we smoke, and the radiation we receive. Moreover, as outlined by Sir Richard Doll, there is also positive evidence that environmental effects are important. Japanese have a lower incidence of cancer of the digestive tract than Americans; but when Japanese move to America, they develop American habits and get the American incidence.

14. At this point, I feel it is important to provide some perspective for the term "environmental origin." A recent editorial in the *Journal of the National Cancer Institute* by Drs. Ernst L. Wynder and Gio. B. Gori (Attachment I) provides a thorough evaluation of the significance of the environmental origin finding. The basic conclusion of the article with which I fully agree is that lifestyle factors such as cigarette smoking, alcohol consumption and improper diet are the prime causes of "environmental cancer" and that food additives, air and water pollution, and toxic chemicals in the workplace are relatively minor contributing factors to the world's cancer problem.

15. The significance of lifestyle factors is not the least surprising when one considers that the 90 percent "environmental cancer" estimate was derived by comparing cancer rates from around the world and attributing any excess cancer mortality above the lowest rate found anywhere in the world for a particular cancer to environmental factors.

16. There is, as yet, no big upsurge in cancer. But two facts urge society to be cautious. The biggest increase in cancers, as shown in Figure 2, has been in lung cancer. These are now almost all attributed to cigarette

smoking. The increase in men followed by 30 years an upsurge in cigarette smoking by men in the 1920's, and the increase in women is just beginning—again following by 30 years a postwar upsurge in cigarette smoking by women. No other types of cancer have shown such dramatic increases, and no other is responsible for such a large number of cases. Although cancer of the colon has been attributed to the diet of the Western World, there is debate on what the actual cause is; some people argue that Westerners eat too much meat, others that they eat too little fibrous cereals. In any event, mortality from such cancers has shown a slight decline over the last thirty years.

17. Since the Second World War there has been a massive increase in the use of industrial chemicals—many of which do not exist in nature. This suggests that society should exercise caution because if some of these chemicals are carcinogenic, we may get an increase of cancer comparable to that caused by cigarette smoking, but delayed by some period of latency. After the first cases have appeared, it is too late to prevent most of the later ones. But we should remember that benezne has been used for over 50 years, and at concentrations far exceeding these presently allowed, so that this general argument does not apply in this case. The issue in this case is not whether one should exercise caution, but how much caution; excessive caution can prevent otherwise desirable actions.

ESTIMATING THE RISK ASSOCIATED WITH EXTREMELY SMALL DOSES

Tests on Humans

18. One possible way of measuring cancer incidence or toxic effects is to try the chemical out on 1,000,000 American workers, and if there is trouble, correct it. For obvious reasons, this is not acceptable. If we started exposing Americans to an unknown chemical, we might be inducing a lot of cancers and not know for 20 years; then society might be unwilling to stop as in the case

of cigarettes. Even if we stopped, the cancers would keep on coming because of past doses.

19. Of course, if for any reason a mistake has been made in the past and some people have inadvertently been exposed to a carcinogen at a high concentration, we must study its consequences so that we may learn for the future. Much of our present knowledge of cancer comes from such mistakes: cigarette smoking, radiation cancers (mistakes of medical men for the most part, but also Hiroshima and Nagasaki), asbestos occupational cancers, and vinyl chloride occupational cancers. Now, we want to assess the risk associated with the production of a chemical in the workplace.

Tests on Laboratory Animals

20. The most practicable method for determining carcinogenesis is to test it on animals. We use *mammals* with a short reproductive cycle—mice and rats. In their lifetime these are believed to approximate man with a longer lifetime in their genetic mutations and cancer incidence. This method has been verified for some cancers where, due to human error, human data exists. Smoking and radiation (from Hiroshima, Nagasaki, and incorrect use of X-rays) and vinyl chloride are examples. Even if we accept the idea that one species is a surrogate for another, we still have a problem. We want to test a chemical suitable for use by 1,000,000 people. If we are to test at the dose level which we are interested in using, and want to be sure that not more than one person gets a cancer in a generation, we need far more than 1,000,000 rats or mice. Typical mice experiments use only 100 mice in attempting to establish the absence of a cancer threat for 1 million people. Obviously, using a larger number of mice would strengthen the assurance obtained from such tests; however, the presence of background cancers due to other causes makes the use of even 1,000,000 mice too few to reduce the risk of cancer in a generation of 1,000,000 people to zero.

21. One solution is to test with mice at a higher level than that at which man might be exposed and find

some way of interpolating the result down to low dose levels that correspond to practical application. Interpolation procedures have been aired very much in the public press in the last three months as a result of the Food and Drug Administration's proposed ban on saccharin as a food additive. The extrapolation of animal data to man has been the subject of two rule making documents published in the *Federal Register* in the past 4 months. The interpolation procedure and the extrapolation from animal to man are major uncertainties.

The Dose-Effect Relationship

22. There are several possible procedures for interpolation between the measured points at high doses, and zero effect at zero dose: the prime requirement of any such interpolation is that it gives a conservative estimate of the risk associated with a given dose level.

23. The conservative extrapolation procedure I use is the linear method. In this method it is assumed that a direct proportionality exists between the size of the dose and the incidence of cancer. Other witnesses will testify that there is a threshold for most carcinogens, below which there is no carcinogenic effect. I neither accept nor deny this assertion but merely state that the assumption is unnecessary to establish acceptability.

Risk is a Function of Average Concentration Over a Long Time

24. If we assume that a linear plot is correct, then the only way to obtain zero risk is if there is zero dose. At extremely low doses, however, the risk may be so extremely small as to be insignificant, and hence, should be acceptable. The first step to approximating this risk is to obtain an estimate of the appropriate dose for basing the risk extrapolation.

25. At this point it may be useful to outline the crucial parts of the Armitage-Doll [1] multilinear theory of

[1] P. Armitage and R. Doll., "The Age Distribution of Cancer and a Multi-Stage Theory of Carcinogenesis," *British Journal of Cancer*, Volume VIII, No. 1, Page 1 (1974). (Attachment II).

cancer incidence. This is a theory of cancer incidence at the level of a cell derived from the age distribution of cancer in human populations. A theory based on mechanisms for formation of the disease would be preferable, but we know too little about cancer for such a treatment. Nonetheless, advances in numerical work in the last 20 years, particularly by Sir Richard Doll, now Regius Professor of Medicine at Oxford, have improved our understanding a lot. It is an important part of the improvement in understanding that we no longer talk about whether a chemical is a carcinogen or not, but what is its carcinogenic potency.

26. It is assumed necessary for a cell to receive $k + 1$ mutations before a cancer occurs. Each mutation is caused by some insult, the probability of which is proportional to time and to the concentration of the substance causing the insult. If people are exposed all their lives this leads at once to the formula for the probability of getting a cancer at the lifetime, t, and in the time dt.

$$dN/N = (p_1 t)\,(p_2 t) \ldots (p_k t)\,(p_{k+1} dt)$$

Then the rate of increase of the population due to cancer is

$$\frac{1}{N}\frac{dN}{dt} = \lambda t^k$$

Experimentally $2 < k < 8$ and depends upon the site of the cancer, and not on the environment; λ depends upon the environment. I have derived this formula from a theory. In fact, this formula is a fit to the observed cancer incidence. Armitage-Doll derive the theory from the formula.

27. Although this theory assumes a *particular* mechanism, the same formula can be obtained from several mechanisms. However, they have in common several features which are generally experimentally correct.

(a) There is a latent period between an individual insult and the cancer observed.

(b) A synergism is predicted whereby cancer incidence can be proportional to the product of the concentration of 2 substances—this has been observed for radiation and smoking, for asbestos and smoking.

(c) If an individual substance causes only one of the insults, then the cancer incidence is linear with the concentration of that substance as often observed.

I do not wish to go into detail about these theories, but I do want to emphasize that inherent in models of this type, particularly those which assume linearity, is that the *parameter which matters is the concentration of the substance averaged over a long time—an appreciable fraction of a lifetime.*

28. As noted above, there are repair mechanisms which may make the cancer incidence less than linear at low doses and at low dose rates (see Appendix A). Accordingly, the pessimistic linear theory shows that taking the concentration averaged over a long time is pessimistic also. This fact, however, enables us to calculate a risk using simple arithmetic; if this risk is low; there is no need to go further and ask whether this pessimism can be removed by a more complicated calculation.

Mutagenicity

29. Meselson [2] has shown that one can in many cases obtain a *quantitative* correlation of mutagenicity with carcinogenicity. This is consistent with the idea that both mutagenesis and carcinogenesis are a function of the change of a DNA molecule. This linear relationship would be expected if pure strains of bacteria and pure strains of animals, without repair mechanisms, are used. Although there are carcinogens which are not mutagens, this is not expected for organic compounds provided that yeast or liver extract is used to mimic the metabolic behavior of the human liver and gut, and mutagenicity will in most cases tell us about carcinogenicity, since there are no repair mechanisms.

With this background, it is appropriate to look at the data. There are three sets.

(a) As of June 27, 1977 [3] no mutagenesis has been observed. The background is about 100 revertants per

[2] M. Meselson and K. Russell paper appended as Attachment III.

[3] Personal communication from Dr. Ames' group at the University of California at Berkeley.

plate and no mutagenesis is observed with quantities of benzene up to 100 μg in the strain TA 100 both with and without liver extract to provide metabolities. This suggests that benzene is at most a weak mutagen, 10,000 times weaker than aflotoxin as shown in the graph from Meselson's paper. (See Figure 3).

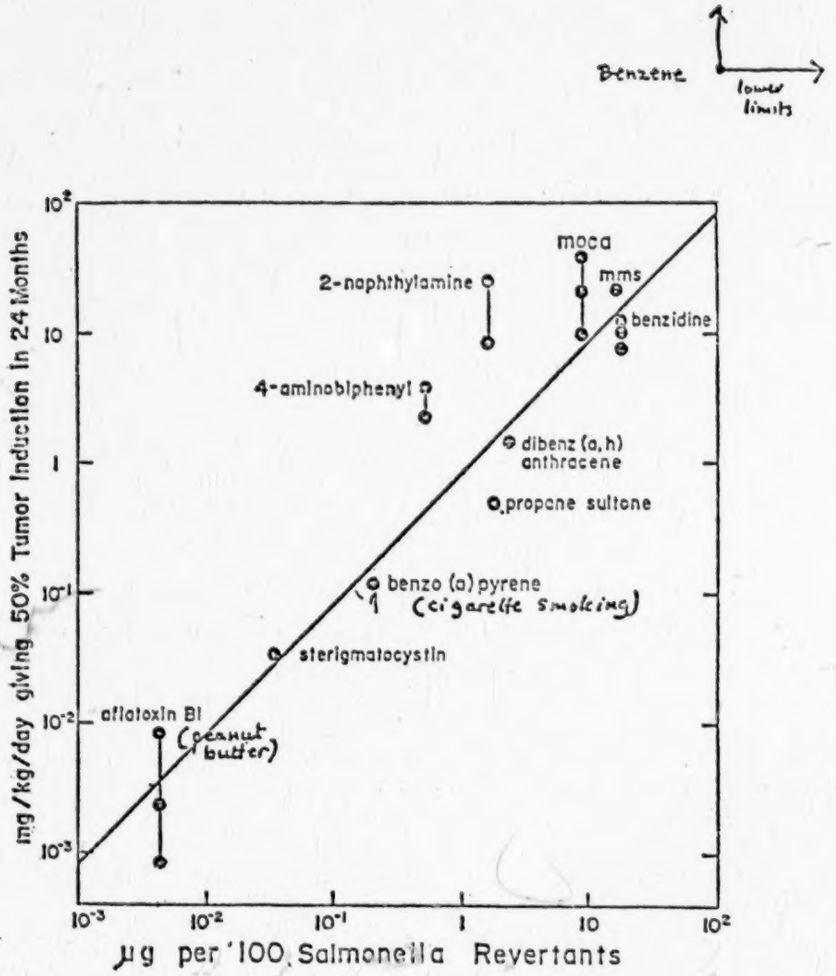

Figure 3
from Meselson

(b) There have been several animal experiments in which attempts have been made to find leukemia induced in mice or rats. These have been primarily by a limited number of sub-cutaneous injections.[4] In one experiment leukemia appeared to have been induced in mice but despite some attempts, that experiment has not been duplicated. None seem to have been by lifetime inhalation studies.

(c) Clinical and epidemiological studies.

These are by Aksoy, Vigliani, Thorpe and Infante.[5] They are inconsistent. I have plotted them in the attached graph in Figure 4. I note that according to our ideas, at this low incidence of leukemia, the incidence should be proportional to dose, or less than this at the lowest dose.

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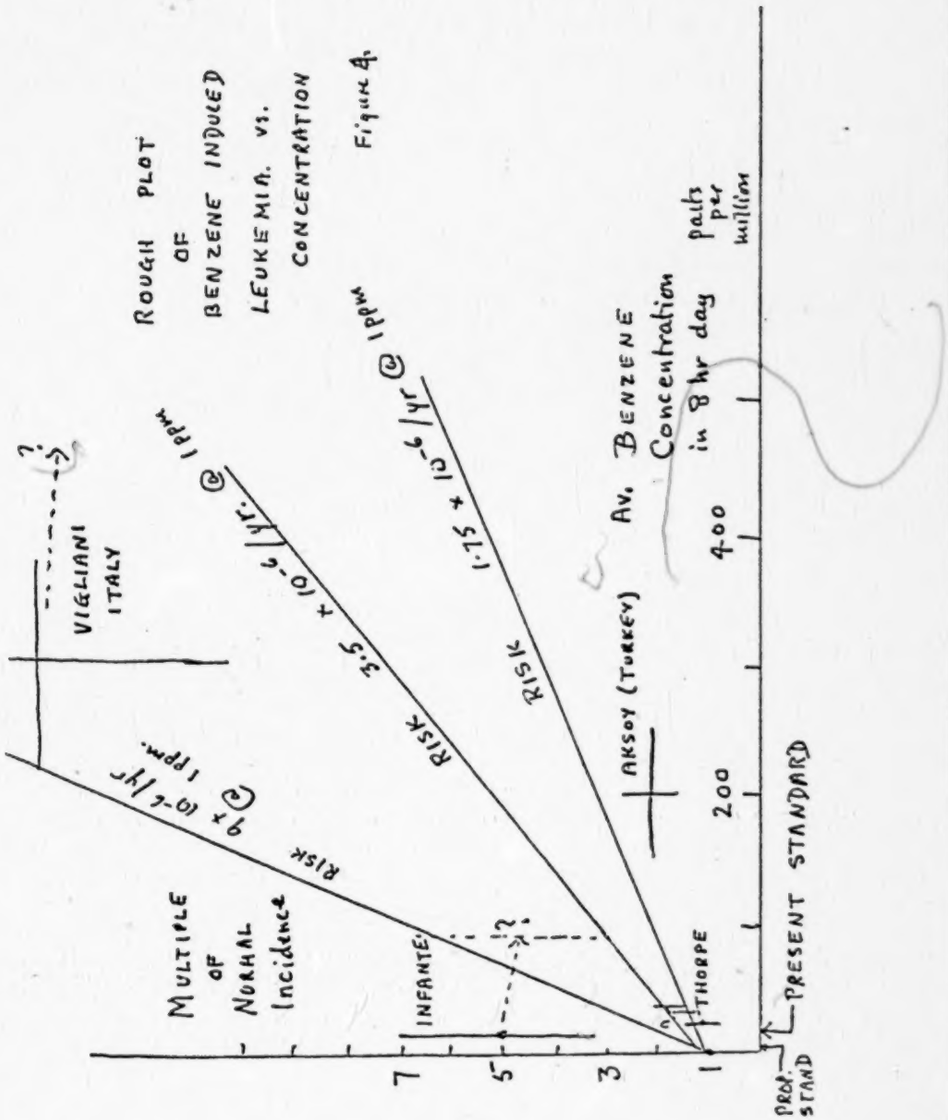
[4] Experiments listed in the *Federal Register* 42, 103 27470 May 27, 1977.

[5] Federal Register 42, 103, 27468 May 27, 1977.



Others may comment in detail on the Infante study. I note here, however, that if the numbers of patients and dose are taken seriously, then there should be a fifty fold increased incidence of leukemia among Turkey's shoemakers, (Aksoy's study) which could not have been missed. There are many questions to be asked about the Infante Study.

Accordingly, I believe that the Infante data cannot yet be taken literally, but I take a figure for leukemia of 1.8×10^{-6} yearly risk at 1 part per million concentration averaged over an 8-hour working day. This is derived from the line drawn on the graph by noting that the normal leukemia incidence in the USA is 15,000 per year (5% of all cancers and 0.75% of all deaths) and that the benzene exposure will increase leukemia not only among the workers, but this increase will continue until old age in spite of retirement! This may be too pessimistic by a factor of 3, since the deaths *expected* by Infante are 0.3%.

I conservatively assume for every leukemia there is one additional cancer at an unknown site, and find a risk of

3.5×10^{-5} yearly at 10 ppm 8-hr. working day

1.4×10^{-4} yearly at 10 ppm continuous exposure

10 ppm in the air adds about

0.7 mg/kg daily to the body weight.

Thus, we can plot the assumed cancer incidence on the graph of figure 3 from Meselson's paper and note that the data confirms that not only is benzene *at worst* a weak mutagen, it is, as expected, *at worst* a weak carcinogen.

THE BASIS FOR INSIGNIFICANCE

30. Table I presents a sampling of the risk associated with a number of man-made and natural occurrences that we face everyday. Although everyone knows that riding in a motor vehicle presents a risk, this risk rarely factors into the decision to make a given trip. At a risk three

orders of magnitude smaller than that of being killed in a motor vehicle accident, no one reasonably worries about being killed in a hurricane; this risk is simply too small to be of concern.

TABLE 1

INDIVIDUAL RISK OF EARLY FATALITY BY VARIOUS CAUSES [6]

(Average Overall U.S. Population in 1969, except as noted)

Accident Type	Total Number For 1969	Approximate Individual Risk Early Fatality Probability/yr
Motor Vehicle	55,791	3×10^{-4}
Falls	17,827	9×10^{-10}
Fires and Hot Substances	7,451	4×10^{-5}
Drowning	6,181	3×10^{-5}
Poison	4,516	2×10^{-5}
Firearms	2,309	1×10^{-5}
Machinery (1968)	2,054	1×10^{-5}
Water Transport	1,743	9×10^{-6}
Air Travel	1,778	9×10^{-6}
Falling Objects	1,271	6×10^{-6}
Electrocution	1,148	6×10^{-6}
Railway	884	4×10^{-6}
Lightning	160	5×10^{-7}
Tornadoes (1953-1971 Average)	118	4×10^{-7}
Hurricanes (1901-1972 Average)	90	4×10^{-7}
All Others	8,695	4×10^{-5}
All Accidents	115,000	6×10^{-4}

31. If we assume a linear relation between cancer incidence and dose it is possible to make a set of simple tables. In Table 2, I have listed a number of hazards, many of which can and possibly should be subject to public attention, for which I have calculated the risk in a very similar manner and with assumptions similar to

[6] Much data assembled by Nuclear Regulatory Commission, NUREG 75/014, and Baldewixz, W., *et al.*, UCLA-ENG-7485, November 1974. See also Statistical Abstract of the United States.

those used to calculate the risk from benzene. These are mostly hypothetical risks. Specific assumptions as to each hazard are discussed in the Appendix. In Table 3 I have listed a number of occupational hazards. Since a risk of 1 in 1 million (or 10^{-6}) is hard to grasp, I have listed in Table 4 several calculated risks of 1 in a million. Some of these are listed in a paper by Sir Edward Pochin.[7]

32. It can readily be seen from Tables 3 and 4 by comparison to hazards which are generally accepted by society that occupational exposure to benzene presents an insignificant risk.

TABLE 2

INDIVIDUAL RISK OF EARLY FATALITY BY VARIOUS CAUSES [8]

(Average Overall U.S. Population in 1969, except as noted)

Accident Type	Approximate Individual Risk Early Fatality Probability/Year
Saccharin, from total consumption	2×10^{-6}
Radiation Cancers: background radiation	1.5×10^{-5}
diagnostic x-rays	1×10^{-5}
1 cross-country airplane flight/year	5×10^{-7}
Cigarette Smoking (Smokers only)	3×10^{-3}
Nonsmoker living with smokers (cancer risk only)	1.5×10^{-6}
Cancer (All types)	1.5×10^{-3}
Air Pollution (U.S. average all sources)	1.5×10^{-4}

[7] E.E. Pochin, The Acceptance of Risk, British Medical Bulletin *31* 184 (1975). (Attachment IV).

[8] See Appendix for discussion of risk estimate for each hazard.

TABLE 3

Annual Risks of Death in Selected Occupations

Coal mining	—	Black lung disease	10^{-2}
Coal mining	—	Accident	1.5×10^{-3}
Airline Pilot	—	Accident	$5 \times 10^{-10-4}$
Typical Jet flying	—	Air accident	10^{-4}
Manufacturing (total)			5×10^{-5}
Benzene worker (10 ppm)	—	cancer	3.5×10^{-5}
Radiation worker at the maximum of 5R/yr		(all cancers)	7.5×10^{-4}
Fire fighters			10^{-3}
Steel worker			6×10^{-4}
Railroad worker		(accident risk)	4×10^{-3}

TABLE 4

Risk of 1 in 1 Million

0.7 cigarette	(cancer, heart disease)
1/2 bottle wine	(cirrhosis of the liver)
10 tablespoonsfull peanut butter	(aflotoxin in mould causes cancer)
1 gallon chlorinated drinking water	(chloroform causing cancer)
30 diet sodas	containing saccharin causing cancer
1 minute	mountain climbing
6 minutes	canoeing
1 air trip Bos.-Was.	(accident risk for either pilot or passenger)
1 air trip (transcontinental)	(cancer risk by cosmic radiation)
1 hr. in a coal mine	(black lung)
3 hr. in a coal mine	(accident)
1-2 weeks	average manufacturing industry
2 weeks	(additional hazard Benzene at 10 ppm)
1 day air pollution in Boston or Washington	

(for some more of these comparisons, and other details, see the paper by Sir Edward Pochin)

The significance of the risk can be seen in still another way. We can ask how much society should pay to reduce the risk. It is in this sense that we should interpret the word "feasible." If we spend all the U.S. gross national product on benzene exposure, we can reduce the concentrations a great deal. But should we do this?

If society spends too much on one risk, the gross national product would soon be exhausted; we can ventilate and put in automatic equipment in coal mines; we can install better equipment, longer runways and better lights at all airports. We can have an army to select unflawed peanuts where the mould containing aflotoxin does not reach the nut. We can install traffic lights, and reduce our efficiency by having a 5 mph automobile speed limit. Any given expenditure may well be considered unfeasible, since too large an expenditure in one occupation can lead indirectly to a *reduction* in safety in other occupations.

If Society wishes to reduce the hazards in various occupations, surely it is preferrable to start on those occupations which are the most risky, and spend money there?

There is some hint in the proposed regulations that the permitted average concentration is being reduced because there is lax enforcement, and that by reducing the standard, the actual concentration can be reduced. But there is practically no correlation; the way of improvement is to enforce the standard; not to change it.

If we apply this concept to the numbers here, each person selling a cigarette should pay a charge of 70 cents *per cigarette* (half of this is a cost to society as a whole and should pay for hospital costs, fire damage, etc.).

In a study performed for OSHA [9] it is estimated that the proposed standard will affect 150,000 people, of which now only 1/5 (or 30,000) have 8 hr. working day average concentrations above the proposed 1 ppm standard.

[9] Compliance tests for benzene emergency standard. U.S. Dept. of Labor, Occupational Safety & Health Administration, May 1977 page 6, 2nd paragraph.

Assuming, for the sake of illustration, that the study is correct, then most of these 30,000 will be exposed at concentrations close to the lower limit so I will assume that 30,000 people are *now* exposed to an average of 3 ppm with an average yearly risk of 10^{-5} at this level. Only a few hundreds would be regularly exposed at 10 ppm. The calculations give 1 leukemia and 1 other cancer throughout all the USA every 6 years. And I reiterate that the number of leukemias and cancers could be zero.

Perhaps industry should try to reduce even this if it is "feasible." It is to be expected that there will be disagreement over what are the costs of this proposed reduction. However, even the lowest figure, calculated in the above OSHA study is $40 million for 6 months corresponding to a cost of $120 million for every hypothetical life saved. Accordingly, I conclude this reduction is not feasible because it will cost too large a fraction of the GNP and leave too little money for other safety measures such as reduction of air pollution, which would yield a much greater dividend in human life.

33. In the proposed emergency standard which precipitated this hearing, the implication is made that the previous Benzene standard took no account of possible carcinogenicity, and that *one* study alone, the Infante study, makes a big change necessary. It is noteworthy that a recent National Academy of Sciences Study on the health effects on benzene [10] reviewed the literature, and found no *proof* of carcinogenesis; only the questionable Infante study has been produced since then. The authors of National Academy of Sciences Studies are rarely reluctant to recommend government action. I find no urge for a reduction of the benzene standard in that document.

34. For all the foregoing reasons, I have concluded that the risk associated with the existing 10 ppm average benzene concentration is so insignificant that it should,

[10] National Academy of Sciences, National Research Council, Health Effects & Benzene, Summer 1976, referred to in Federal Reports, 42, 103 27470 (May 27, 1977).

in my opinion, be acceptable. This conclusion is gained by comparison with the risk associated with other occupational hazards. Even if the Infante study is taken literally, there is no emergency. The risk would still be only equal to the average risk in all manufacturing industries.

APPENDIX A

35. The risk associated with each of the hazards listed in Table 2 has been calculated in a manner similar to that for Benzene exposure. The basis for calculating the risk associated with each hazard is summarized below. For illustrative purposes, the risk estimate for radiation cancer due to one (1) cross-country airplane flight per year is provided in detail.

Cigarette Smoking

36. Here the risk is directly assessed from human data. The risk for nonsmokers living with smokers is roughly estimated from a comparison of the volumes of smoke laden air consumed. Some of my anti-smoking friends think that this may be a "meaningless exercise" since the risk is small and the curve may be non-linear. For comparative purposes, the number certainly has meaning. About 40% of the hazard of cigarette smoking is a cancer hazard; the rest, increased heart disease, etc., it is possible that increased heart disease accompanies other carcinogenic agents in the same proportion, even at lower doses. If so, all other risk calculated from carcinogenic effects must be multiplied by 2.5. The comparisons remain valid.

Saccharin

37. This comes from animal data at high doses and an extrapolation to the *known* total consumption of saccharin in the U.S. The number here comes from the testimony of Dr. Marvin Schneiderman to the Rogers Committee of the U.S. House of Representatives.[11] I have checked his numbers and agree with them.

[11] See also *Federal Register*, April 15, 1977, page 20001.

Radiation

38. Radiation cancers have been studied in humans and animals. I take the numbers here from the Report of the Committee on Biological Effects of Ionization Radiation (BEIR) of the National Academy of Sciences, November 1972. This uses a linear interpolation for low doses also. Radiation works directly on the cell and avoids problems with toxicity at high dose levels.

39. There have been tests with over one million mice at the Oak Ridge National Laboratory. These suggest that the effect at low dose rates is 1/4 of that calculated from this linear curve. This reduces the number from background radiation, but probably not those from diagnostic x-rays or jet airplane flights where the dose is rapid. It is often stated that chemical carcinogens give a smaller insult than radiation, and to this extent a low dose rate effect probably occurs for chemicals. The numbers here remain conservative upper limits.

The Risk of Travelling By Air

40. We are used to the ordinary risk of air travel which is the risk of accident. At the present time, air travel is fairly safe: one death for 300 million miles of travel on a scheduled air carrier.[12] The risk is, of course, concentrated at take off and landing. Nonetheless, I use this to get a figure for the risk of accident for one 3000 mile (cross country) flight; it is 3000/300 million or 10^{-5} One such flight per year gives a risk of 10^{-5} per year.

41. These cross-country airplanes travel at an altitude of 35,000 feet (10 kilometers.) At this height there is an appreciable dose due to cosmic radiation, including neutrons. To estimate this, I use the UNSCEAR report.[13]

[12] Airplane accident deaths often come 100 at a time and the fluctuations are large. Nonetheless, this figure seems to be coming down in the domestic USA; one death in over a billion miles.

[13] Report of the United Nations Scientific Committee on the Effects of Atomic Radiation, UN, NY, 1962, page 201, figure 1. It might be thought that the neutrons would be absorbed by the airplane and the body. Since they are in equilibrium with the surrounding air, this can be allowed for by taking the dose at a lower altitude from the figure. This is a small reduction. (Attachment V).

The dose at a latitude of 55′ N is 2000 millirems/year of ionizing radiation and 3600 millirems/year of neutrons. This will increase markedly during a period of a solar flare.

42. Using 365 days a year, a 5 hour flight at 10 km gives a dose between 3 and 4 millirems. Now, using the relationship between cancer incidence and whole body dose in the BEIR report,[14] I find a cancer risk of 5 x 10^{-7} per transcontinental flight. This is smaller than (1/20 of) the risk of accident and is normally neglected in any discussion of the risks of airplane travel. But it is derived on a comparable basis to the cancer risks discussed here and helps to put them in perspective.

Drinking Water

The numbers here are taken from a recent National Academy of Sciences report.[15] I have made similar calculations, And I am in general agreement. I assume a level of chloroform in the drinking water of 100-200 parts per million (less than reported in New Orleans & Miami). Chloroform has been shown to be carcinogenic in rats and mice.

[14] "The effects on Populations of Exposure to Low Levels of Ionizing Radiation," *Report of the Advisory Committee on the Biological Effects of Ionizing Radiations.* (BEIR) National Academy of Sciences/National Research Council, November 1972.

[15] *Summary Report: Drinking Water and Health,* National Academy of Sciences, National Research Council, Committee on Safe drinking Water, Advisory Center on Toxicology, Assembly of Life Sciences, May 1977. Page 49, table 1. (Attachment VI).

[The following materials are from the administrative record on the percentage-exclusion amendment to the standard. Immediately following are excerpts from the reporter's transcript for May 23, 1978.]

* * * *

[13] QUESTIONS DIRECTED TO MR. WRENN BY MR. LETTOW

MR. LETTOW: Thank you, Judge Ramsey. Mr. Wrenn, during the hearings now under way on the Agency's proposal to establish a generic regulatory structure for carcinogens, you reportedly testified that, and I quote, "Feasibility has consistently been interpreted to mean technical and economic feasibility." End quote. To your knowledge, is this statement an accurate reflection of the Agency's position?

MR. WRENN: I think it is. Not necessarily a full and complete discussion of the issues involved in determining feasibility, but I think that is an accurate expression in the limited form that it is.

MR. LETTOW: Well, the key part of that particular quoted phrase would be an assessment of both technical and economic factors, and the Agency does carry out such an assessment. Is that correct?

MR. WRENN: That has been correct, yes.

MR. LETTOW: Arthur D. Little's study for OSHA, in this benzene—in the original benzene proceeding—focused only on arriage of mixtures containing greater than 1 percent benzene. Has OSHA now updated the A. D. Little study to cover the range from zero to 1 percent?

MR. WRENN: I believe that it is fair to—there has been no additional study of that specific nature; however, [14] the Arthur D. Little study represented only one element of the record on which this issue was ultimately assessed; the preamble of the final benzene standard sets forth the basis for the determinations of the feasibility of the standard as a whole, and the basis for dealing with this issue of percentage exclusion and the feasibility of including or not including such provisions.

MR. LETTOW: Well, maybe I should ask the question in a slightly different way. Does the Agency plan to update the A. D. Little study to cover mixtures with less than 1 percent benzene, specifically?

MR. WRENN: We look to the testimony in this hearing to provide the basis for determining the feasibility and advisability of establishing a percentage exemption for mixtures containing trace amounts of benzene, and what that exemption should be.

MR. LETTOW: In short, you will consider feasibility in making the determination as to a percentage exclusion?

MR. WRENN: Certainly.

MR. LETTOW: What other factors, aside from technical and economic matters, generally will you consider in making this determination?

MR. WRENN: Well, I am not sure that I could usefully give you a catalogue of factors that would enter into every aspect of decisionmaking on health standards, but one need only [15] look at any one of the major health standards to see the range of scientific, technical and policy issues that are considered in establishing the various aspects of the regulation.

MR. LETTOW: This proceeding is following on a number of further proceedings, both before the Agency and courts and you are very familiar with those proceedings. Do you have some specific issues and factors that you plan to address in making the determination as to a percentage exclusion?

MR. WRENN: The proposal which triggered this proceeding attempts to set forth those issues, and I think it adequately does so. I could restate those issues, but I do not think it would be useful to do so.

MR. LETTOW: By those issues you mean the nine questions?

MR. WRENN: Yes. And the context of the proposal itself, the discussion of those issues.

MR. LETTOW: Does OSHA plan to consider dermal exposures in establishing a percentage exclusion?

MR. WRENN: The proposal does not distinguish between various routes of exposure to benzene. It simply raises the question of whether it is necessary and appropriate to establish an exemption to amend the final standard for benzene by establishing an exemption from coverage of any of the provisions of the standard—mixtures containing so-called trace amounts of benzene. And the exemption as proposed in the [16] Federal Register notice would be an exemption from all provisions of the regulation.

MR. LETTOW: Question six says, "What airborne concentrations of benzene result from the percentage of benzene in each product?" Is that going to be a special factor in making the determination as to a percentage exclusion?

MR. WRENN: That is certainly a matter of interest to the Agency in setting any exemption for benzene-containing substances. Since the standard itself establishes a permissible exposure limit for benzene, we would certainly endeavor to set an exemption which assured that employees exposed to materials exempt from coverage under the regulation are subject to no greater exposure than employees who are subject to the provisions and protection of the standard.

MR. LETTOW: Why is there—

MR. WRENN: One of the questions that was raised in the earlier rulemaking and one of the questions that is raised here is the question of the likelihood that exempting any particular category of materials from regulation, under the benzene standard—the likelihood that that exemption would provide a basis for being confident that workers involved with those exempt materials would not be exposed in a manner that was intended to be avoided by the benzene regulation.

MR. LETTOW: Why is there not then also a comparable question or a point specifically addressed toward dermal [17] exposure?

MR. WRENN: I suppose primarily—as a practical matter, primarily because there is no quantitative measure in the benzene standard or any other regulation dealing with toxic substances such as benzene—no quantitative measure is typically associated with dermal contact with materials like benzene. And yet, inhalation exposure is readily quantified and a fundamental aspect of the regulation is usually the establishment of some limit to the exposure to airborne vapors and gases.

MR. LETTOW: Does OSHA have any factual information on levels of dermal absorption of benzene, beyond the very small amount of information in the original hearings in standard-setting proceedings?

MR. WRENN: I am not fully aware of the materials we have received to date in this proceeding. The preamble to the final standard for benzene discussed the evidence in the record which was related to the dermal hazard from benzene.

MR. LETTOW: I will try that one again a different way. Does OSHA have any current plans to obtain dermal absorption data?

MR. WRENN: No. Other than through the normal process of acquisition of information of this sort for benzene and a host of other toxic substances.

MR. LETTOW: Does OSHA have any current work of any [18] kind under way to determine whether or not a hazard exists from dermal exposure to mixtures containing small amounts of benzene? That is, within the range that we are talking about with this percentage exclusion.

MR. WRENN: What do you mean by work under way?

MR. LETTOW: Do you have any studies now being performed by contractors, or do you have any plans, for example to have contractors perform any such studies?

MR. WRENN: That is not generally the nature of OSHA's activities. We look to other parts of the scientific community, including NIOSH, NCI and the academic and private and research activities to provide the information on which we assess the hazards of worker exposure to toxic substances and establish regulatory requirements.

MR. LETTOW: Does NIOSH have any such work under way, or have you worked with NIOSH to establish a program for collecting such information?

MR. WRENN: I am unaware of work of this nature under way by NIOSH.

MR. LETTOW: Has OSHA studied the desirability or necessity of establishing a dermal contact limit, similar to the permissible exposure level for air contaminants set in the standard?

MR. WRENN: OSHA has recognized the importance of—and particularly, the current Assistant Secretary, Dr. Bingham—[19] has recognized the importance of skin contact with toxic substances in the workplace as being a major factor in occupational disease, ranging all the way from acute dermatitis to chronic disease, or the contribution to the risk of chronic disease from skin absorption of toxic substances. And because of that, we have established an Ad Hoc Standards Advisory Committee which is meeting during this time to evaluate the importance of percutaneous absorption and other means of skin contact with toxic substances in the workplace, and to recommend to the Agency appropriate regulatory actions to deal with these problems.

JUDGE RAMSEY: Mr. Lettow, you have about 5 minutes.

MR. LETTOW: That is fine, I just have several more questions and then I am ready to sit down. I think it is my cold, but in any event, what is OSHA's present timetable for acting in these rulemaking proceedings?

MR. WRENN: For acting in which rule—

MR. LETTOW: In these.

MR. WRENN: In this present.

MR. LETTOW: That is correct.

MR. WRENN: The instant proceeding, as you would say. Our intention, as we have indicated in our opening remarks and in the proposal, and before the courts is to act as expeditiously as possible. I do not have a publication date that I can give you for a final decision by the Agency, but we do intend to [20] issue a final decision on the basis of the record developed in these proceedings as rapidly as possible.

MR. LETTOW: I am going to ask you to make some assumptions that I will give you as a hypothetical case. Assuming that a study were now under way of absorption

of benzene through skin, and that the results of such a study could be made available to OSHA within 180 days, would you change your projected timetable in acting in these particular proceedings?

MR. WRENN: No, sir.

MR. LETTOW: All right. Your Honor, I think that is going to do it. With that, we will turn it over to you or someone else.

MR. WRENN: Let me add to the answer to the last question. I am rarely allowed to get away with a yes or a no in these proceedings.

(Laughter.)

MR. WRENN: I would add that one of the basic charges that OSHA has, from the Congress and through the Occupational Safety and Health Act, is to set standards for protection of workers based on the best available evidence. And in this case, we have already concluded a rulemaking, a lengthy rulemaking, a rulemaking which involved extensive public participation, and we believe the record in that proceeding represents the best available evidence for setting a standard [21] for benzene. On the one narrow question of the scope of this regulation which covers benzene which has been described as a ubiquitous material and arising in many forms in the workplace and in the consumer environment, we have determined that it was appropriate to reexamine the issue of scope and the issue of percentage exclusion because there appeared to be evidence that was not brought to the record of the original proceeding that would be immediately available for consideration by the Agency. In that sense, it would be inconsistent with the purposes we have set for this rulemaking to defer further decision on this matter for a period as long as 180 days or any other significant period.

Now, if information comes available on benzene or any other regulated substance, or unregulated substance, which significantly changes the perception in the scientific community and the regulatory community of the hazard of exposure to a substance or the appropriateness of existing regulation, it is our business to examine

that evidence and to reexamine any actions we have taken or not taken in the face of that new evidence, and we would do so. But I think the earlier answer of "no" is an appropriate response to the question of whether we would defer decision in this proceeding for as long as 180 days, awaiting the results of a study, the nature of which results could not possibly be known at this time.

[22] MR. LETTOW: Your Honor, I think I liked the "no" answer better, but then in any event, I just have one further question after that statement. Would you agree, Mr. Wrenn, that in effect the percentage exclusion level would act as the permissible exposure limit for dermal contact in the standard, as the standard is now written?

MR. WRENN: I do not think it serves in any analogous way as a quantitative and readily measurable airborne exposure limit.

MR. LETTOW: Well, I did not say airborne exposure limit; I was actually referring to the fact that if you had a permissible or a percentage exclusion, would that percentage exclusion act to exempt someone from the dermal contact provisions of the standard?

MR. WRENN: The percentage exclusion, as we contemplated it and as the proposal discusses it and as the earlier rulemaking discussed it, is simply—it simply acts to alter the scope of the regulation; that is, determine whether it applies or does not apply. It, I think, serves no purpose other than that. That is an important purpose. Surely the scope of a regulation is a very important aspect of a regulation. But I think that it would be meaningless to characterize the scope of the application as serving, in the way we normally think of a permissible exposure limit, as a permissible exposure limit.

[23] MR. LETTOW: Mr. Wrenn, would you agree that the scope of the various sections of the standard that bear on the airborne contaminant levels is affected by the action level concept?

MR. WRENN: Most of the requirements of the regulation are deemed to apply or not in relation to the degree of employee exposure. For those employments

covered by the scope of regulation, in both the action level and the permissible exposure limit, play a role in determining which of the obligations of the standard apply in any given set of exposures.

MR. LETTOW: Thank you, Your Honor.

* * * *

[126] STATEMENT OF ROGER W. STRASSBURG, DIRECTOR OF ENVIRONMENTAL AFFAIRS, B.F. GOODRICH COMPANY

DR. STRASSBURG: Your Honor, Judge Ramsey, ladies and gentlemen, I am Roger S. Strassburg, Director of Environmental Affairs for the B.F. Goodrich Company. With me today on the panel are Ernest Bean, Assistant General Counsel of the B.F. Goodrich company, and on his right, E.T. McDonel, Manager of Tire Materials Research [127] of B.F. Goodrich Tire Division, and on my left, Carl Draves, Jr., Director of Materials and Compound Development, of the B.F. Goodrich Tire Division. What we have done is to prepare a written statement that examines in detail nine questions that the Agency asked concerning possible revisions in the benzene standard. This statement and supporting documents have been submitted prior to this hearing in order that they may become part of the record of the proceedings, and they are noted as S2, I believe, and I would like to move that they become a part of this record.

* * * *

DR. STRASSBURG: I hope that the information that we have submitted will help you in the development of a suitable percentage exclusion, whereby certain work operations will not be included in the scope of the final benzene standard and I hope that our statement gives you some perspective for [128] the concerns that Goodrich has regarding the final benzene standard as it was promulgated in February.

Rather than reading directly from our written, I would like to review briefly the main points that we believe should be considered when reformulating the permanent standard for controlling the use of benzene in the work-

place. After my presentation my colleagues and I will be happy to try to answer any questions that you may have.

As you know, Goodrich participated in the original benzene rulemaking. At that time, we urged that the standard not apply to work operations where liquid mixtures containing one percent or less of benzene are used. However, any concept of a proposed percentage exclusion was deleted when the final standard was issued, and Goodrich is now unable to comply with that standard. In fact, the present standard provides unsolvable problems for us because of the very nature of our operation. Two of our domestic divisions manufacture tires and other rubber products. These operations used petroleum solvents that contain trace amounts of benzene. Another division of our company manufactures cements, adhesives and sealants and therefore uses various grades of petroleum solvent containing residual benzene.

Another division produces and uses various raw materials commonly referred to as petrochemicals, which are derived from petroleum and thus have trace amounts of benzene.

[129] Therefore, Goodrich has a vital stake in any standard that applies to benzene, and to help construct a more realistic standard we have three recommendations. First, provide for an exclusion level of a tenth percent benzene or less in liquid mixtures below which the standard does not apply. Second, establish a special action level of a half a percent benzene in liquid mixtures for the dermal contact sections of the standard only. And third, re-write the labeling provisions of the standard so that the "cancer hazard" label does not apply to liquid mixtures or products containing unavoidable benzene contamination.

I would like to discuss each of these in turn. Goodrich's particular concern, aside from labeling and dermal contact, with a regulatory strategy without a percentage exclusion is that such a strategy is imprecise and lacking in objective criteria whereby appropriate health precautions are initiated. Benzene is renown for its ubiquity. Yet, the mere presence of benzene, however minute, in

liquid mixtures automatically triggers significant regulatory requirements, such as initial monitoring, training, recordkeeping, the dermal contact prohibition and labeling. A standard based on this premise is simply not realistic. Let me illustrate why this is the case.

Using special analytical instrumentation called a gas chromatograph mass spectrometer we have detected [130] benzene concentrations in the range of one to six parts per billion in process water used at one of our manufacturing facilities. Furthermore, we believe that benzene has been present in significant parts per billion in all petroleum-based organic materials that have been analyzed to date. And benzene may be present in minute quantities in other raw materials and products. In addition, the National Academy of Sciences recently announced that benzene had been detected in drinking water.

Therefore, with a final benzene regulation to remain in effect without a specified percentage exclusion, we believe the standard would be quite arbitrary and unreasonable. In fact, the fact that a scientifically sophisticated employer had the analytical capability to detect benzene in liquid solutions where benzene is clearly a trace contaminant could trigger regulatory compliance. In fact, by providing a drinking fountain an employer could be subject to the initial monitoring, training, recordkeeping, dermal contact prohibition, labeling provisions of the standard. Clearly, without a percentage exclusion we could venture into the realm of unreality.

A specified percentage exclusion is needed to eliminate such concerns. A specified percentage exclusion might also eliminate, to a substantial extent, the controversies over whether compliance by Goodrich or other companies [131] is feasible.

As a consumer of various types of petroleum-based solvents, we find ourselves at the mercy of suppliers concerning the benzene content in their products. Goodrich's specification for the level of residual benzene in rubber-freshening solvent has fluctuated from two and a half percent to two-tenths percent, depending upon the commercial availability of low benzene solvents. Since late

1977, our benzene specification has remained at a half a percent and all of our rubber-freshening solvent suppliers have met that specification.

Lower specifications, however, jeopardize supply and would require the entire rubber industry to rely on the one supplier that at this time has been able to reduce benzene content to meet the requirements of the proposed tenth percent benzene standard. To expect a single supplier to meet the entire industry's need for solvent is completely unrealistic, particularly when only one-half of the entire industry needs can be met in the foreseeable future. Likewise, it is not feasible, either technically or economically, for us to remove benzene from the solvent after they have supplied it to us. Therefore, Goodrich and the entire rubber industry is dependent upon our suppliers in the petroleum industry to reduce the residual benzene levels in their products to the lowest feasible levels obtainable [132] by their technology.

Since it is virtually impossible for us to receive solvent without some trace of benzene, we support strongly the concept of a specified percentage exclusion at some level for the reasons previously stated. However, Goodrich cannot support and strongly objects to the proposed one-tenth percent benzene exclusion level for liquid mixtures, as applied to the dermal contact prohibition section of the standard. As a member of the rubber industry, Goodrich requests relief from the dermal contact prohibition section above and beyond the proposed tenth percent benzene percentage exclusion. Our proposal is that OSHA adopt a special action level of half a percent benzene in liquid mixtures for the dermal contact section of the standard. We call our proposal a special action level in order to emphasize that it would apply only to the dermal contact sections of the standard. It would be distinct from the general tenth percent benzene exclusion proposal. We believe it is essential that a half a percent level for dermal contact be established for several reasons.

First, the tire industry cannot operate without some dermal contact with rubber-freshening solvent that is contaminated with trace amounts of benzene. The actual building of tires and the critical placement of layers of

rubber-stop require that at least a portion of the fingers [133] or palm of at least one of the builder's hands comes into contact with the swab used to apply the freshening solvent. We have studied the possibility of completely avoiding dermal contact with solvent by the use of gloves or barrier cream. Our research indicates that protective gloves are not practical; in fact, they are unsafe. Barrier creams do represent a possible way to protect workers from the absorption of benzene into the skin. However, the use of barrier creams poses such problems as the effect they would have on the adhesion properties of cured tires. Moreover, the use of barrier creams would require constant monitoring to ensure that the correct amount of the cream was applied at the proper intervals, possibly up to six times during an eight-hour shift. Therefore, at this time we believe that further studies are necessary before the unqualified use of barrier creams can be endorsed.

There is a second reason why a special action level should be adopted for skin contact. The standard as it is now written, calls for a prohibition against dermal contact but is not supported by scientific evidence. Skin absorption is recognized as a secondary health hazard and should be regulated as such. The present standard ignores this fact. The primary hazard presented by benzene exposure—that is inhalation—is permissible at levels up to one PPM/TWA. Yet in the case of potential skin absorption, which is a [134] secondary hazard at best, the standard prohibits skin contact with liquid altogether. We challenge the reasonableness of a standard that permits some exposure to a carcinogen via the primary route of entry and prohibits any exposure from the secondary route of entry.

Our third reason for supporting a change in the dermal contact standard is that a special action level does not prevent other protective measures from coming into operation. For example, if Goodrich or others in the rubber industry are unable to obtain a tenth of a percent benzene rubber-freshening solvent, and are forced to use a half a percent benzene concentration solvents in order to build tires, a special action level in no way exempts us

from the initial monitoring, training and recordkeeping provision of the standard. Thus, workers would be protected while what OSHA admits is a very real problem for industry would be solved. We believe that relief from the present provisions of the standard regarding dermal contact are absolutely essential and we would urge that a special action level of a half a percent benzene be adopted.

Also of concern is the provision of the standard that deals with labeling. As I mentioned earlier, Goodrich supports the proposed percentage exclusion of a tenth percent because of its elimination of regulatory activity triggered by the presence in the workplace of ubiquitous benzene as a [135] trace contaminant in liquid mixtures. If triggering of the labeling provision is not eliminated, along with the elimination of such requirements as initial monitoring and employee information and training, Goodrich would be faced with the unsolvable problem of not knowing what it was required to label because of lack of an objective standard for determining the presence or total absence of benzene. Moreover, there should be no requirement for the cancer hazard label on mixtures containing benzene in concentrations between the percentage exclusion and those permitted by a special dermal contact action level. There is no evidence of a cancer hazard from touching such liquids, and labeling them would be confusing to our employees. All possible health effects including dermatitis could best be explained as a part of the employee information training program.

Therefore, Goodrich believes that the labelling provision of the standard as promulgated is unnecessary, and we strongly urge that OSHA, in this present rulemaking, rewrite the section of the standard involving labeling.

From my remarks and from the comments of others testifying today, I am sure you can appreciate the importance we attach to the final benzene standard. My comments today reflect our concern that the final standard achieves workplace health without presenting insurmountable problems to our industry. I am hopeful that a standard accommodating these [136] dual objectives will emerge from this hearing. Thank you, and we would be happy to try to answer your questions.

* * * *

QUESTIONS DIRECTED TO DR. STRASSBURG BY SOLICITOR'S OFFICE

MR. ESTEP: Now, let me see if I have got this straight. You are the ones with the blimp, is that right?

DR. STRASSBURG: We are the other guys.

MR. ESTEP: First let me see if I understand your position as far as this proposed dermal action level. You are suggesting that a tenth of a percent exclusion hold across the board. However, for purposes of whatever that very special section on scope and application concerning the dermal exposure, that there be an exclusion of five-tenths of a percent only for dermal?

DR. STRASSBURG: Right.

MR. ESTEP: So this would mean that a tire builder, while he can touch five-tenths of a percent, would still have—the employer would still have to meet the permissible [137] exposure limit of one part per million in the ambient air. Is that correct?

DR. STRASSBURG: That is right.

MR. ESTEP: So that the employer who is working—an employee who is working with a solvent of three-tenths of a percent, he can touch it but the ambient air still has to be below one part per million.

DR. STRASSBURG: Right.

MR. ESTEP: And let me again make it clear that that is your proposal; it is not—that was not articulated in the proposal for this rulemaking, but it is an alternative.

DR. STRASSBURG: Right.

* * * *

[139] MR. ESTEP: On page 13 of your statement at the bottom, without getting into the question of health effects, you have mentioned, "Further calculation indicates a maximum actual skin absorption of a tire builder's use of one percent benzene rubber-freshening solvent would result in approximately one-third the exposure permitted by the permissible exposure limit." I wonder if you can explain what you mean by that. I know that you

have in your research section, which is D, some data there, but it is a fascinating statement and if it were true, it could have some effect on this dermal action level that you are suggesting. I think it is on page three of D. Do you want to direct me?

DR. STRASSBURG: Okay, I have page three now.

MR. ESTEP: I am asking you to explain that correlation. I think on page three of D, under (a), is some sort of an explanation, but I would like you to [140] clarify that or explain it.

[141] DR. STRASSBURG: I am going to ask Mr. McDonel if it is all right to do that.

MR. ESTEP: Certainly.

MR. MCDONEL: What we tried to do was sort of an experimental calculation to determine what sort of dermal exposure a worker would do in a worst case situation, and here we attempted to be very conservative, much like accountants do, and we obtained the data that if a worker were exposed to one part per million benzene—this was the action level, or the maximum permissible level in eight hours, that according to the industrial hygiene and toxicology reference we gave there, he would be exposed to about 28.8 milligrams of benzene in eight hours.

Are you with me so far?

MR. ESTEP: I think so. You are saying that if he is going to breathe so much of a volume of air, the total exposure over a time weighted average, an eight-hour time weighted average, would be approximately 28.8?

MR. MCDONEL: Yes, we used this as a base reference. We wanted to know on how much maximum exposure a tire builder could come in contact with over an eight hour period.

MR. ESTEP: Does this approach have any scientific precedent in calculating total exposure to a substance? Or is this sort of a new approach taken by you?

MR. MCDONEL: Well, maybe this is our original [142] approach. We felt that we needed to have some basis in order to put some perspective on how much benzene exposure would a tire maker be exposed to, and

we wanted to know what the exposure level was just from the one part per million level. We did a calculation in Part A, and that is the calculation we came to there.

MR. ESTEP: Okay.

MR. MCDONEL: And then we took a very conservative estimate. We know the number of exposures that a tire builder will have on an eight-hour shift in building a tire in a worst possible case situation.

MR. ESTEP: And that is 30 contacts?

MR. MCDONEL: Yes.

MR. ESTEP: And that is where he takes the fabric swabs—

MR. MCDONEL: Yes.

MR. ESTEP: —and he rubs it on a tire—

MR. MCDONEL: Yes.

MR. ESTEP: —and he puts the swab back?

MR. MCDONEL: Yes. Only we did it in a much more conservative way. We determined how much solvents your hand would pick up if you dipped your hand in up to the wrist, to determine the loss or the amount of solvent your whole hand would pick up. Now, this is a factor of ten to 100 excessive, really, because you do not really pick up that [143] much, but we wanted to have some sort of basis for judgment and if, you know, rather than guessing, we just decided to try it and find out.

MR. ESTEP: How did you calculate the amount to remain on the hand?

MR. MCDONEL: We put the solvent in a glass beaker and weighed it on a scale, and then we dipped our hand into it, removed the hand, and noticed the loss in weight.

MR. ESTEP: You dipped the hand in and out?

MR. MCDONEL: Yes. It is a very simple experiment.

(Laughter.)

JUDGE RAMSEY: Your question, Mr. Estep.

MR. ESTEP: Could you proceed with the—

MR. MCDONEL: The explanation?

MR. ESTEP: Yes, the explanation.

MR. MCDONEL: Well, then it is very simple mathematics to calculate the amount of the benzene exposure, if you would assume that all of the benzene that was in the rubber solvent at that time went through the skin, which again—

MR. ESTEP: But that is an assumption you are making that that amount is absorbed.

MR. MCDONEL: That is the assumption we made, and that is not a true assumption, necessarily.

MR. ESTEP: Okay.

[144] MR. MCDONEL: This was just for a matter of calculation, a matter of comparison.

MR. ESTEP: This accounts for your later statement that it is a worst case analysis, far in excess of actual exposure?

MR. MCDONEL: Yes.

MR. ESTEP: Okay.

MR. MCDONEL: This merely puts the thinking in perspective as to where we stood when we were—just what were we exposing the tire builders to? And I think that this is a very important calculation, because it had not been done, and nobody really came up with objective comments as to what was the extent of the exposure on the dermal contact. I believe that calculation puts some perspective on that.

MR. ESTEP: Then your conclusion is, then, it is roughly equivalent or it is less?

MR. MCDONEL: Yes, than the permissible one part per million time weighted average.

MR. ESTEP: And that is the worst case analysis, which could be 100 times greater than the actual exposure? This is not based on any scientific data which suggests rate of absorption?

MR. MCDONEL: No, it is not. It is only based on the amount of solvent contact that would be done. Now, we [145] have rerun those experiments in which we have been more realistic, and found that instead of the 2.94 grams pick up which we have there, we have come out more with a three-tenths per gram pick up if you just

dip your fingertips in to the first knuckle, or the second knuckle.

MR. ESTEP: Okay, thank you.

* * * *

[209] STATEMENT OF ROY N. JOHNSON,
THE GENERAL TIRE AND RUBBER COMPANY

* * * *

[210] MR. JOHNSON: Yes. My name is Roy Johnson and I am Corporate Director of Safety and Health for The General Tire and Rubber Company. I will be presenting General's comments on the proposed amendments to the benzene standard.

Each of General's three major divisions, the tire division, chemical division, and industrial products division, is affected by the permanent benzene standard. Each of these divisions involves high volume production operations which use solvents containing small amounts of benzene.

I want to emphasize that these operations cover a broad range of products ranging from tires to tennis balls to materials for luggage, footwear, shower curtains, credit cards and to plastic parts for the auto industry. Clearly, General's 15,000 products cover all sections of the nation's economy.

[211] General long ago recognized the hazardous nature of pure liquid benzene. With the exception of perhaps some necessary laboratory applications, no liquid benzene is used by the company. However, as noted, large quantities of commercial solvents and adhesives are utilized and essential to the continued operation of General's manufacturing facilities which affect a broad spectrum of the nation's business and industry.

Due to the Company's large volume requirements, laboratory grades are unavailable in sufficient quantity. Rubber makers' solvents, as well as various other solvents and adhesives used by the Company do contain some percentage of benzene as a naturally occurring contaminant, and General knows of no source of commercial grade solvents or suitable solvent substitutes which are totally benzene free.

I would now like to address the issues outlined in OSHA's announcement of this proceeding very briefly. With respect to the question of whether there should be a percentage exclusion, General believes that certain work operations should be exempt from the standard where the sole exposure to benzene is from liquid mixtures containing less than a specified percentage of benzene. General believes that the present strict prohibition against skin or eye contact with liquids containing any amount of benzene is unreasonably restrictive.

First, the restriction is unreasonable in light of the unavailability of commercial grade rubber makers' solvents, [212] or printing ink solvents that are totally benzene free.

Second, although General's operations are highly automated, certain operations, such as the assembly of tires, as you have previously seen, or the assembly of tennis ball components, require the accuracy of hand assembly, making total avoidance of skin contact with solvents an impossibility.

General therefore believes that an exemption from the skin and eye contact prohibition is absolutely required so that critical manufacturing processes in production of numerous consumer and industrial products can continue. In the absence of such exemption, General and the rest of the industry would be required to elect between stopping production or continuing operation in violation of OSHA's permanent standard.

General also believes that if the percentage of benzene adopted as the exemption level is sufficiently low, exemption from the provisions of the entire standard would be appropriate. However, in the absence of a total exemption, there must be relief from the impossible situation created by the provisions prohibiting dermal and eye contact.

General does not believe that the 0.1 percent benzene is the appropriate percentage for an exemption. We, as well as other members of the rubber industry, require large volumes of commercial grade solvents. Based upon availability in the marketplace, my company believes that a minimum of 0.5 percent, and ideally, 0.7 percent, would

be an appropriate percentage [213] upon which to base an exemption for the dermal and eye contact. Solvents at or below 0.5 percent appear to be available in sufficient quantities to allow most industrial locations to continue operations. And while it is true that some suppliers are able, at least on occasion, to supply solvents to some geographic locations as low as 0.1 percent benzene content, these same suppliers are not able to supply the needs of the entire industry or to guarantee a consistent quality at such low levels.

The Company would also support a planned reduction in the adopted percentage but believes that such reduction should only be adopted when the solvent producers have the capability to deliver commercial grade solvents in sufficient quantity and at consistent levels of benzene content.

Rubber makers' solvents utilized in the manufacture of such items as tires, tennis balls and rubber industrial and commercial products vary considerably with respect to the benzene content. General has been monitoring shipments at various facilities throughout the country, and in recent experience found only one shipment exceeding one percent. Most suppliers fall within a range of 0.2 percent to 0.75 percent.

Benzene levels in some limited number of shipments have measured 0.1 percent or less, but only one or two small suppliers known to General seem to be able to deliver 0.1 percent or lower solvent on a consistent basis. [214] It should be noted that these suppliers are unable to supply General's needs let alone those for the entire industry. I am told by our technical staff that other petroleum derivative solvents are not acceptable substitutes, and in most of these a trace amount of benzene is found to exist also.

On a related issue, you have asked how far can the benzene content of products be feasibly reduced. General does not have sufficient knowledge to respond to this question.

General studies conducted to date indicate as a rule the lower the benzene content of the solvent, the lower the individual exposure to airborne exposures. From a

0.1 percent benzene solution and 0.5 percent benzene solution, such factors as work practices, nature of the operation, and air handling equipment appear to have a more significant impact on airborne concentrations than does the benzene at levels at or below 0.5 percent.

Where the percent of benzene in solvent is at or below 0.5 percent and the work operations are properly controlled, most employee exposures to airborne concentrations remain below the permissible level. There are, however, some exceptions and even a 0.1 percent solution could produce exposures above the actual level.

General believes that if a dermal exemption is granted at 0.5 percent, airborne concentrations can be held below the action level with improved work practices and air [215] handling equipment.

With respect to labeling, General believes that liquids exempted from the benzene standard due to their extreme low percentage or benzene content should also be exempted from the labeling requirements of the standard. First, uncontrolled use of the warning label certainly dilutes the effectiveness of the warning message.

Secondly, if the lower percentage of benzene in the liquid reduces the hazardous nature of the solution sufficiently to entitle it to exemption from the other provisions of the standard, there appears to be no logical reason to require manufacturers to undertake the time consuming and expensive process of applying labels to otherwise safe containers of liquids.

As the last member of the rubber industry witnesses, I would like to take a moment to summarize my view of the industry's position. Each of the rubber companies, as well as the RMA, has indicated support for a percentage exclusion. The data which has been submitted indicates the percentage exclusion should be at least 0.1 percent.

But the rubber industry has a special problem which requires more than a percentage exclusion. Given the need for dermal contact in tire building and other operations, the rubber industry requires a special exemption level for dermal contact with liquids with small amounts of benzene. That [216] special dermal exemption level

should be set at 0.7 percent benzene or a minimum of 0.5 percent benzene.

Because of the industry's dependence on outside suppliers, perhaps the best approach would be a 0.7 percent level initially, to be reduced in stages to a 0.5 percent as suppliers can meet the lower levels. The results of Dr. Maibach's study which was discussed earlier certainly should bear directly on the exemption level finally chosen.

Thank you very much for the opportunity to testify.

* * * *

[Amend Exh. 32-F-2]

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

No. 78-1486

THE RUBBER MANUFACTURERS ASSOCIATION, INC., *et al.*, PETITIONERS,

v.

EULA BINGHAM, As Assistant Secretary of Labor for Occupational Safety and Health, *et al.*, RESPONDENTS.

On Petition for Review of Action by the Assistant Secretary of Labor for Occupational Safety and Health

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MOTION FOR STAY

TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT, THE HONORABLE JUDGES THEREOF:

Petitioners in the above-styled cause respectfully move this Court to stay the effectiveness of Sections (c)(2), (h), and (k)(2)-(5) of the permanent benzene standard (29 C.F.R. §§ 1910.1028(c)(2), (h) and (k)(2)-(5)) as promulgated by Order of the respondent, Eula Bingham. These portions of the permanent benzene standard are the subject of the Petition for Review in this proceeding.* This motion is made on the grounds that petitioners are likely to prevail on the merits of this Petition

* The Petition for Review was initially filed in the U.S. Court of Appeals for the Sixth Circuit, and docketed there as No. 78-3114. By order of the Sixth Circuit entered on March 9, 1978, the Petition for Review was transferred to this Court, because of the pendency of the prior-filed petitions for review in *American Petroleum Institute, et al.* v. *Occupational Safety and Health Administration*, Nos. 78-1253 and 78-1257 (5th Cir.).

for Review, they will be irreparably harmed unless a stay is granted, no substantial harm will be incurred by other interested persons through grant of a stay, and there will be a benefit to the public interest and no harm to the public interest through grant of a stay. The grounds upon which this motion are based are more fully set forth in the accompanying Memorandum of Points and Authorities in Support of the Motion for Stay and the affidavits attached thereto.

On March 3, 1978, application for a stay was made to respondents. At 3:35 p.m. on March 9, 1978, counsel for Petitioners received a "statement" of respondents' intention to grant partial relief. A copy of this "statement" is attached. To counsel's knowledge, as of the time of filing this motion the respondents have not actually granted any relief.

Oral hearing is requested if the Court should deem it appropriate.

Respectfully submitted,

/s/ Charles F. Lettow
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Counsel for Petitioners

OF COUNSEL:

CLEARY, GOTTLIEB, STEEN & HAMILTON

March 10, 1978

U.S. DEPARTMENT OF LABOR
Occupational Safety and Health Administration
WASHINGTON, D.C. 20210

Office of the Assistant Secretary

The following statement was made orally on March 8, 1978 to parties seeking a response by that date to their requests for an administrative stay by OSHA of certain provisions of the permanent benzene standard, 43 Fed. Reg. 5918-5970, Feb. 10, 1978. Individual written responses to the various parties will also be made. The text of the oral statement is as follows:

Except as stated below, we are denying the parties' requests for relief:

1. The agency is correcting the preamble to the benzene standard in a correction document which will be available at the Federal Register Office as soon as possible. That document will state that OSHA interprets the reference to solids in the definition of benzene to apply only to pure solid benzene and *not* to solids which contain benzene.

2. OSHA is going to stay the standard as it applies to work operations where the sole exposure to benezene is from mixtures containing 0.1% or less of benzene. This decision will be announced in a Notice of Proposed Rulemaking and Notice of Stay in the Federal Register and OSHA will be soliciting additional information on the percentage exclusion issue. This decision will be announced in an official news release either this week or early next week.

[Amend. Exh. 32-F-2]

* * * *

AFFIDAVIT OF JAMES R. SANKEY
OF THE GOODYEAR TIRE & RUBBER COMPANY
IN SUPPORT OF MOTION FOR STAY

STATE OF OHIO)
) ss.
COUNTY OF SUMMIT)

JAMES R. SANKEY, being duly sworn, deposes and says:

1. I am now and have been for the past three years Director of Domestic Tire Production for The Goodyear Tire & Rubber Company ("Goodyear"), an Ohio corporation with its principal offices located in Akron, Ohio. I have been employed by Goodyear for thirty five (35) years in various capacities relating to the manufacture of tires for automobiles, trucks and other wheeled vehicles and have managed tire plants in Akron, Ohio; Union City, Tennessee; and New Delhi, India. I am personally familiar with all aspects of the process of manufacturing automobile, truck and related type tires.

2. Goodyear is the world's largest manufacturer of tires and produces more tires in the United States than any other tire producer.

3. As Director of Domestic Tire Production, I am directly responsible for the operations of eight (8) domestic tire manufacturing plants owned and operated by Goodyear. These facilities are located in Akron, Ohio; Danville, Virginia; Gadsden, Alabama; Jackson, Michigan; Los Angeles, California; Madisonville, Kentucky; Topeka, Kansas; and Union City, Tennessee. Collectively, these facilities employ more than 15,695 persons in manufacturing and related operations. I am personally familiar with all aspects of the operations at each of these facilities.

4. I have read and am familiar with the permanent standard of the Occupational Safety and Health Admin-

istration for the regulation of occupational exposure to benzene (29 CFR 1910.1028, 43 *Fed Reg* 5917, Feb 10, 1978) (the "Benzene Standard"). I have particularly reviewed the sections of the Benzene Standard dealing with dermal and eye contact with liquid benzene, 29 CFR 1910.1028(c)(2) and (h) (collectively referred to as the "Dermal Contact Sections").

5. As written, Goodyear is unable to manufacture tires in compliance with the Dermal Contact Sections of the Benzene Standard, as described below. Goodyear will suffer irreparable harm if the Dermal Contact Sections of the Standard are not stayed.

6. The use of petroleum solvents is essential to the manufacture of tires. These petroleum (or "rubber") solvents are used as tackifying agents in the tire building process. The manufacture of tires involves, among other things, attaching layers of material ("plies") together to construct tires. Solvent is applied with a swab to each tire ply and other components' surfaces to insure sufficient adhesion for the components to hold a fixed position during the building operation. Precision tolerances are critical for tire uniformity and compliance with safety standards. Tires are built on a moving drum, and excess liquid solvent can be splattered or thrown off in the process. All placement and fitting of component parts is done manually by the builder, and the operator's hands are in constant contact with surfaces that have been activated by petroleum solvents containing benzene. This manual contact with surfaces is essential to the builder, not only in applying layers of material to the tire, but also detecting wrinkles and other defects in the ply application from the "feel" of the tire. The degree and frequency of dermal contact with these solvents varies with the size and type of tires being built, and the speed at which the building drum rotates. The larger the tire being built, and the larger and heavier the component plies, the more solvent will be used and the more the operator's hands must be in contact with the tire surface. There is no suitable substitute for the use of petroleum solvents in this process.

7. Petroleum solvents suitable for the tire building operation contain trace amounts of benzene as an impurity. Goodyear has requested all major suppliers of petroleum solvents to provide Goodyear with solvents that do not contain any amount of benzene. These suppliers advise Goodyear that it is not feasible to remove all the benzene from petroleum solvents used in the construction of tires.

8. To comply with the Dermal Contact Sections of the Benzene Standard, it would be necessary for employees engaged in attaching plies to wear face and eye protection, protective clothing, and gloves or other protective covering for the hands. In the builidng of certain types of passenger car and radial tires, the introduction of more automated building machinery may permit the operator to wear protective gloves, as the need for sensitive manual contact with the tire during building is reduced. On other tire types, such as farm and tractor, and off-the-road tires (earthmover tires, etc.), even if it were possible for employees to effectively perform their functions while wearing gloves, it is not possible to equip them with skin-tight, impervious gloves which would not dissolve or become tacky upon contact with petroleum solvents. Gloves would also be subject to adhesion and build-up of softened, solvent-activated rubber during ply application, and gloves would require frequent change, perhaps as frequently as a change after each tire is built, and the impact of such a procedure on the tire building process would be severe.

9. The inability of Goodyear to comply with the Dermal Contact Sections of the Benzene Standard in the tire building process is one critical example of compliance problems with the Sections. On information and belief there are several other areas of Goodyear's tire and rubber products manufacturing operations where Goodyear would be severely hampered by the Dermal Contact Sections.

10. Compliance with the Dermal Contact Sections of the Benzene Standard will cause Goodyear irreparable injury and will bring domestic tire production to a virtual standstill.

11. In reviewing the Benzene Standard, I have also given particular attention to the subsections relating to requirements for affixing caution labels to all containers of benzene and of products containing any amount of benzene, 29 CFR 1910.1028(k)(2)-(5) (the "Labeling Sections"). Compliance with the Labeling Sections will cause Goodyear irreparable harm.

12. It is not possible for Goodyear to adjust its manufacturing and shipping procedures relating to tires in order to comply with the Labeling Sections before the effective date of those Sections. Accordingly, compliance with the Labeling Sections of the Benzene Standard will effectively bring a halt to Goodyear's shipments of tires.

13. The Kelly-Springfield Tire Company ("Kelly-Springfield") and Lee Tire & Rubber Company ("Lee") are wholly-owned subsidiaries of Goodyear which are engaged in the manufacture and sale of tires and which employ more than 9,395 persons in manufacturing and related operations. On information and belief, compliance with the Dermal Contact Sections and Labeling Sections of the Benzene Standard by Kelly-Springfield and Lee would bring tire production at Kelly-Springfield and Lee to a standstill.

14. I further state that the above matters are based upon my personal knowledge except where otherwise noted, in which case they are based upon information and belief.

Dated this 8th day of March, 1978.

/s/ James R Sankey
JAMES R SANKEY

* * * *

AFFIDAVIT OF ROGER W. STRASSBURG OF THE B.F. GOODRICH COMPANY IN SUPPORT OF MOTION FOR STAY OF OSHA'S PERMANENT BENZENE STANDARD

I, Roger W. Strassburg, being duly sworn, do hereby state as follows:

1. I am currently employed by The B.F. Goodrich Company (Goodrich) at its corporate headquarters at Akron, Ohio in the capacity of Director of Environmental and Energy Affairs, a position I have held since 1977, prior to which for over five years I was Director of Environmental Affairs. The responsibilities of these positions include the coordination at the corporate level of all activities of Goodrich with respect to health, safety and environmental concerns. The organization of Goodrich includes various divisions involved in corporate support services, of which my function is a part, and several operating divisions. The domestic operating divisions are the Tire Division, the Engineered Systems Division and the General Products Division, all headquartered at Akron, and with which I am particularly involved, and the Chemical Division headquartered at Cleveland, Ohio.

2. I received a Bachelor of Science degree in Chemistry from Iowa State University in 1942 and a PhD degree in Organic Chemistry from the University of Minnesota in 1950. I joined Goodrich in 1951 and held various research and technical positions until 1969. In 1969 I was appointed Administrative Assistant to the President of Goodrich's Industrial Products Division (now a part of its Engineered Systems Division) and became Director of Environmental Affairs for Goodrich in 1973.

3. As part of my present duties I have the responsibility for assessing Goodrich's ability to comply with the permanent standard for occupational exposure to benzene (the "Benzene Standard") promulgated by the Occupational Safety and Health Administration (OSHA) as CFR Sections 1910.1028 at 43 *Federal Register* 5917, et seq on February 10, 1978. While my responsibilities ex-

tend to coordination of all Goodrich activities in connection with the Benzene Standard, including those of the Goodrich Chemical Division, my physical proximity to the headquarters of the Tire, Engineered Systems and General Products Division has led to my personal concentration on the activities of these Divisions. The effect of certain provisions of the Benzene Standard on the operations of the Goodrich Chemical Division is detailed in the Affidavit of Robert A. Krueger of Goodrich Chemical Division in support of Motion for Stay of Permanent Benzene Standard accompanying this document.

4. I have carefully reviewed OSHA's summary of the Benzene Standard and the standard itself as published in the Federal Register. I have particularly reviewed the section of the Benzene Standard dealing with dermal (and eye) contact with "liquid benzene", 29 CFR 1910-.1028(c)(2) and (h), (Dermal Contact Sections) and those dealing with labeling products containing "any amount" of benzene, 29 CFR 1910.1028(K)(2)-(5), (Labeling Sections). In connection therewith I have sought the counsel and advice of professional Goodrich personnel in both the corporate support services and operating divisions of Goodrich including personnel involved in the areas of industrial hygiene, purchasing, analytical sciences, law, manufacturing and marketing.

5. The information set forth herein is based on my personal knowledge and on information supplied to me by such persons.

6. Goodrich's Tire Division manufactures passenger, truck, aircraft, farm, industrial and related types of tires at manufacturing plants located at Woodburn, Indiana (near Fort Wayne); Miami, Oklahoma; Tuscaloosa, Alabama; Oaks, Pennsylvania and Akron, Ohio (non-passenger tires only). Collectively, more than 6,000 persons are employed at these plants in tire manufacturing and related operations.

7. An essential part of the tire building process is the attachment and adhesion of layers (plies) of uncured rubber compound coated on fabric, one to the other. In order to do this it is necessary that workers apply with a "swab" to the uncured rubber compound a small portion of organic solvent which has sufficient rubber solvation ability to impart tackiness to the plies and promote the adhesion. Application of the solvent to enable "unsticking" of plies improperly positioned at the tire building drums is also required, especially with larger sized tires of more complex construction, since precise positioning of the plies is critical in all tires for tire uniformity and compliance with safety standards. The liquid organic solvent must also, of course, have sufficient volatility characteristics to allow a rapid drying rate after application and thus prevent undue delays in the tire building operation.

8. Goodrich has been aware for some time of the health effects of benzene vapors in the workplace and has adapted work practices and controls such as to reduce the airborne concentration of benzene to the lowest feasible level. One of the most significant steps taken has been to procure organic liquid solvents for use in the tire building operation containing such a very low concentration of benzene that the airborne concentration of benzene vapor in the workplace will not exceed 1 part benzene per million parts of air (1 ppm) as an 8 hr. time weighted average (TWA).

9. On May 27, 1977 OSHA proposed a permanent standard for occupational exposure to benzene incorporating the 1 ppm TWA airborne exposure limitation. (42 FR 27452, et seq). However, the proposed standard specifically did not apply to "work operations where the only exposure to benzene is from *liquid* mixtures containing 1% (0.1% after one year) or less of benzene by volume or the vapors released by these liquids." Since Goodrich had already discontinued the use of solvent containing more than 1% benzene in its tire building operations, it submitted only a few comments on the proposed standard. It did not, because of the exemption, specifically address the dermal contact provisions of the proposed standard (which prohibited dermal contact with liquids containing more than 1% of benzene).

10. The Benzene Standard as promulgated removed the exemption. Its Dermal Contact Sections prohibit skin contact with any "liquid benzene" and the definition of

benzene, as well as the "preamble" description, indicate that liquid solvents containing any amount of benzene are included. Goodrich thus had no opportunity to comment on the final Dermal Contact Sections and explain the impossibility of building tires in compliance with these Sections as set forth below.

11. Goodrich has made an extensive search for a source of a liquid solvent for use in tire building which would have the necessary characteristics and contain "no benzene" but has been completely unsuccessful. No solvent or mixture of solvents is available which has the required rubber solvation and volatility characteristics and at the same time is completely free of benzene.

12. In the tire building operation described, the application of the solvent to the rubber compound requires the use of the workers' hands, which despite all feasible work practice precautions inevitably come in contact for the short period until evaporation with some quantity of the liquid solvent. In addition, application of the solvent to the plies as they are positioned on the revolving drum of a tire building machine, despite feasible work practice precautions, produces some "splashing" of the solvent (containing some dissolved rubber) on the worker's clothing with at least a theoretical chance of slight penetration to the skin.

13. It is critical to the tire building operation that the worker applying the solvent retain his manual and movemental dexterity, unfettered by restrictive protective clothing. If the hands are covered by impermeable gloves (as is apparently contemplated by the protective clothing provision of the Dermal Contact Sections) the gloves become "sticky" and may themselves adhere to the rubber stock with attendant difficulties and delays in the operation, perhaps harm to tire quality, and even the possibility of a safety problem. Further, "skin tight" rubber gloves would themselves be attacked by the solvent.

14. For the reasons above, Goodrich will suffer irreparable harm if it were required to comply with the Dermal Contact Sections. It is not now technically feasible for tires to be built without some skin contact with some solvent containing some amount of benzene. New

technological changes in preventing dermal contact with solvent would at best significantly slow down the tire production operations, again resulting in irreparable harm to Goodrich.

15. My study of the record leading to promulgation of the Benzene Standard (which has not for lack of time been complete) leads me to believe that the Dermal Contact Provisions were adopted (and the proposed Standard changed in this respect) without indication that harmful health affects occur through skin absorption of benzene present in small amounts in other liquids. In fact, the preamble to the regulation states that the primary course of entry of benzene in man is through inhalation and that the effect of benzene contact on the skin is essentially unknown. The Benzene Standard through the "action level" provision for airborne benzene does not purport to achieve inhalation control to absolute *zero* (which, of course, is a concept rather than an attainable reality) but there is nothing akin to an "action level" with respect to skin contact and absolute zero absorption through the skin is mandated. Accordingly, I believe there would be no harmful health effects in permitting workers to build tires as described using solvent containing small amounts of benzene and that to require otherwise is completely arbitrary and irrational.

16. The Goodrich Engineering Systems Division manufactures a line of rubber fabricated articles including hose and belts of various types at plants located in Akron, Ohio; Marion, Ohio; Oneida, Tennessee; Elgin, South Carolina; Richmond, West Virginia and Grantsville, West Virginia, at which plants it employs approximately 3,000 workers. The processing and fabricating operations at these plants are such that skin contact with liquid benzene or liquid solvent containing benzene is avoided and the proportion of benzene contained in the materials processed and used is such that airborne benzene concentrations would be expected to be safely below the Standard's "action level".

17. The Goodrich General Products Division manufactures a line of finished and semi-finished rubber and plastic products including many "adhesive products" for use

by industry and the consumer at plants located in Akron, Ohio; Gloucester, Massachusetts; Marietta, Ohio; [illegible]on, Ohio; New Ulm, Minnesota; Salem, Indiana and San Mateo, California with employment of some 2,000 workers. Liquid solvents containing trace amounts of benzene are used in the adhesive products plant at Akron, Ohio and perhaps at other plant locations but again the operations do not involve skin contact with such solvents and the airborne benzene concentration would be expected to be safely below the "action level".

18. However, considering that traces of benzene are present in synthetic rubber and other materials (excluding again liquid solvents containing benzene), used at these plants, and that the Benzene Standard applies to all places of employment where "benzene" without limitation as to amount or form, is "handled or used" it cannot be said that any workplace of these Goodrich divisions is unaffected by the Benzene Standard.

19. Of particular concern are the Labeling Sections of the Benzene Standard as applied to containers of "all products containing *any amount* of benzene" in the workplace and when the containers of finished products and articles leave the employee's workplace. The Labeling Sections seem to require the "Caution-Cancer" label on "containers" for such products not only in the plants of Goodrich's Tire Division but also in plants of its Engineered Systems and General Products Divisions. This will result in irreparable harm to Goodrich in that workers may be led to assume that the benzene in the containers is released to the air in the workplace in concentrations above the "action level" and criticize the plant management for not indicating that the workplace is a "regulated area".

20. Further, the Labeling Sections as applied to the finished products leaving the workplace are not sufficiently objective for Goodrich to know which finished products should bear the label on containers and would cause Goodrich irreparable harm without affect on worker safety for the same reasons as detailed in the aforementioned Krueger Affidavit. Consider as an example what possible good it would do to place a "Caution-Cancer"

label on the wrapper of a tire as it leaves a tire factory simply because the tire is made inpart from a synthetic rubber containing benzene in the parts per million range and there is no specific assurance that the tire manufacturing operations have eliminated the benzene to the point where the tire contains "absolute zero" content of benzene.

Moreover, the line of adhesive products made by Goodrich's General Products Division is so vast and the customers thereof so numerous that I see no practical limits to the downstream effect of the Labeling Sections. Certainly it is virtually impossible for there to be complete compliance with the Labeling Sections, if interpreted literally, in the foreseeable future, and it is absolutely impossible for this to be accomplished by the March 13th effective date of the Standard.

/s/ Roger W. Strassburg
ROGER W. STRASSBURG

* * * *

AFFIDAVIT OF ROBERT E. RHEM OF THE GENERAL TIRE & RUBBER COMPANY IN SUPPORT OF MOTION FOR STAY

Robert E. Rhem, being duly sworn, deposes and says:

1. I am now, and have been since December 1, 1974, Vice President of Manufacturing, Tire Division for The General Tire & Rubber Company ("General"), an Ohio Corporation having its principal place of business located in Akron, Ohio. I have been employed by General for approximately twenty-nine (29) years in various capacities relating to the manufacture of tires for automobiles, trucks, and off-the-road equipment, and have previously served as Production Manager for General's tire plant in Akron, Ohio and as Plant Manager of General's tire plant in Mayfield, Kentucky. I am personally familiar with all phases of the production processes utilized by The General Tire & Rubber Company in the manufacture of tires.

2. As Vice President of Manufacturing, Tire Division, I am directly responsible for the operations of six (6) tire manufacturing plants owned by General and operated within the United States. These manufacturing facilities are located in Akron, Ohio; Bryan, Ohio; Charlotte, North Carolina; Mayfield, Kentucky; Mt. Vernon, Illinois; and Waco, Texas. In addition, I am directly responsible for General's two (2) manufacturing facilities engaged in the production of tread rubber and rubber components, paints and cements for the tire recapping industry, which plants are located in City of Industry, California and Macon, Georgia, and General's facility in Barnesville, Georgia, which manufactures and processes tire cord materials for our tire production operations. These manufacturing operations combined employ more than 8,130 persons in manufacturing and related operations, and directly contribute to the local economy in seven (7) different states. I am personally familiar with the manufacturing operations at each of these production locations.

3. I have read and I am familiar with the Occupational Safety and Health Administration's permanent standard

for regulation of exposure to benzene in the work place (29 CFR 1910.1028, 43 *Federal Register* 5917, February 10, 1978). I have reviewed the provisions of the standard with various knowledgeable individuals within our manufacturing and technical organizations, and presently believe that compliance with most of the provisions of the standard, while difficult, will be attainable.

4. I have also read and reviewed the requirements of the standard relating to dermal and eye exposure 29 CFR 1910.1028(c) (2), protective clothing and equipment 29 CFR 1910.1028(h), and labeling 29 CFR 1910.1028(k) (2). I am informed and personally believe that as these provisions are presently written, The General Tire & Rubber Company will be unable to continue to manufacture tires and at the same time, comply with the above regulations. General will suffer irreparable harm if these provisions are not stayed pending review of the standard.

5. Petroleum-based solvents are essential to the tire manufacture process. Petroleum-based rubber solvents are used to "freshen" or tackify the surfaces of the rubber compounds. The construction of tires involves the assembly or attaching together of various rubber components and plies or layers of material into a finished "green" or uncured assembly. During the assembly process, which is performed on a rotating building drum, solvent is applied with a swab to each tire ply and other component surfaces to insure proper adhesion and maintain components in a fixed position during completion of the building operation. Precision placement of components, and maintenance of components placement during subsequent operations, are critical to tire uniformity and compliance with federal tire safety standards.

6. Placement and fitting of components during assembly is a skilled, manual operation. The tire builder's hands are in constant contact with surfaces that have been activated by solvents containing some amount of benzene. In addition, when the rotating building drum is turned, excess amounts of solvent may be thrown off in the process, and may again come in contact with the tire

builder. General knows of no means by which this skilled assembly process could be automated to eliminate this skin contact with solvents containing some benzene, nor does General know of any suitable substitute solvent for the tire building process.

7. In addition to the tire building process outlined above rubber solvents containing trace amounts of benzene are necessary, critical to, and used in other operations within the tire manufacturing facilities. Rubber solvents are used in the preparation of cements which are applied to various components and, by necessity, these components are handled by employees during the transfer and building and manufacturing processes. Solvents are also necessary in the area of tire repair, where it is necessary to soften or retackify "green" or uncured as well as cured tires in order to make permitted repairs during the manufacturing process. These repairs are of necessity critical, skilled, manually performed operations. Rubber solvents are also used in the retreading and recapping industry, as are cements manufactured using solvents containing trace amounts of benzene, and these operations again require substantial handworking in contact with surfaces treated with solvents. Finally, but not necessarily by way of exclusion, petroleum-based solvents are used in inside and outside "green tire" lubricants applied to the uncured tires prior to curing.

8. Petroleum solvents suitable for tire building and related tire manufacturing operations do contain trace amounts of benzene as an impurity. General purchases these rubber solvents from various manufacturers who have advised the Company's purchasing representative that suitable solvents containing no benzene are not commercially available. After promulgation of the proposed benzene standards, General requested its suppliers to certify that suitable rubber solvents would contain 1% or less of benzene, and General changed its solvent specification to include that minimum requirement. This change in specification was made in consideration of the proposed standard on Occupational Exposure to Benzene 42 *Federal Register* 27452, May 27, 1977, which provided in 29 CFR 1910.1028(a) (ii) an exclusion "to work operations where the only exposure to benzene is from liquid mixtures containing 1% (0.1% after one year from the effective date of the standard) or less of benzene by volume, or the vapors released from these liquids." Solvents in use by General conform to these specifications, but due to the nonexistence of commercially available benzene-free suitable solvents, and due to OSHA's elimination of the one percent (1%) exclusion in this permanent standard, dermal contact with liquids containing benzene cannot be prevented if tire manufacturing is to continue at the General Tire & Rubber Company.

9. I am informed and believe that dermal or eye contact with solvents containing benzene cannot be prevented through the use of protective clothing and eye and face protection. Building, repair, and other skilled manual operations involved in the tire manufacturing process require precision which would be hampered by the use of gloves, if solvent impervious gloves were available which would not dissolve upon contact with rubber solvents and would not become tacky upon contact with rubber cements manufactured with such solvents. General knows of no such gloves or other impervious garments available to the industry. In addition, due to the necessity of using rotating building drums and other forms of moving machinery, the use of protective garments, if available, would create additional safety hazards, and the added risk of injury due to the possibility of protective garments being caught in moving machinery, or due to the hampering of employee's reflexes and dexterity necessary to operate equipment and manufacture tires in a safe manner. On information and belief, production of tires at the General Tire & Rubber Company would be seriously hampered and drastically reduced by the use of such protective garments in order to avoid dermal contact with solvents containing only trace amounts of benzene.

10. For all of the foregoing reasons, compliance with the dermal contact provisions of the standard will cause The General Tire & Rubber Company irreparable injury and bring critical, precision manufacturing in the field of domestic tire production to a halt. For the same reasons,

continued production of tires within The General Tire & Rubber Company would, of necessity, have to be performed utilizing currently known and proven methods, processes and materials, including suitable solvents, thereby forcing General to be in non-compliance with 29 CFR 1910.1028(c)(2) and (h) if the Company is to remain operative in the business of manufacturing tires. It is not possible for General to remain in production and comply with these provisions of the standard at the same time.

11. In reviewing the Benzene Standard, I have also given particular consideration to 29 CFR 1910.1028(k)(2) relating to labeling requirements. This section requires that the employer assure that caution labels are affixed to all containers of benzene and of products containing any amount of benzene. Compliance with this section will cause General irreparable harm.

12. It is not possible for General to comply with such requirement before the effective date of that section, since sufficient time has not been allowed to obtain and affix the vast number of such labels as may be required now that the permanent standard has defined benzene to include all "mixtures of liquids containing benzene". This requirement, in the absence of the prior one percent (1%) exclusion of the proposed standard and Temporary Emergency Standards, will require the Company to review and perhaps analyze the contents of a vast array of solvents, cements, inks, adhesives, and other liquid chemicals used in its manufacturing, laboratory and maintenance operations. In addition, compliance is rendered impossible due to OSHA's total failure to adequately define the terms "containers of benzene" or "products containing any amount of benzene". While OSHA admittedly has authority to regulate hazards in the work place, the employer should not be required to engage in sheer speculation as to what parts or portions of its manufacturing equipment and facilities constitute "containers of benzene", especially in view of the numerous solvents, cements, and adhesives containing only trace amounts of benzene that are used in the rubber industry in both manual and automated application processes. In addition, since the term "products containing any amount of benzene" has not been limited in any way to solid, liquid,

or gaseous products, it is conceivable, although obviously unreasonable, that such labeling provision could be interpreted to include even solid products such as tires and related rubber goods which may contain within their solid form trace amounts of benzene as a contaminant. In the absence of a stay as to this labeling provision, General cannot comply with this portion of the regulation due to the reasons and uncertainties set forth above.

13. I further state that the above matters are based upon my personal knowledge, or upon information supplied to me by competent and knowledgeable persons upon whom I rely, and are true to the best of my knowledge.

/s/ Robert E. Rehm
ROBERT E. REHM

* * * *

AFFIDAVIT OF ROY N. JOHNSON OF THE GENERAL TIRE & RUBBER COMPANY IN SUPPORT OF MOTION FOR STAY

Roy N. Johnson being first duly sworn, deposes and says:

1. I am now and have been Corporate Director of Safety and Health for The General Tire & Rubber Company of Akron, Ohio for the past four years. In addition, I have twenty-two (22) years of experience in the field of Safety Engineering and Employee Health, directly related to the Rubber and Plastics Industries.

2. In my present position, I have the responsibility for establishing Company policy and procedure which will assure a safe and healthy working environment for all employees of The General Tire & Rubber Company. While my job encompasses said areas of Safety and Health for all divisions of the Corporation, this affidavit seeks to explain those Provisions of the permanent Standard which will adversely effect the operations of our Industrial Products and Chemical/Plastics divisions, as differentiated from our Tire Division.

3. I have read and am familiar with the permanent Standard of the Occupational Safety and Health Administration for the regulation of occupational exposure to benzene, 29 CFR Section 1910.1028, published in 43 *Federal Register* 5917, February 10, 1978. I have particularly reviewed the Sections relative to dermal and eye contact and protective clothing.

4. Because the Standard does not specify any lower permissible limit of benzene as a contaminant in petroleum-based solvents, compliance in many of our operations will be impossible, short of total shutdown. Thereby, irreparable harm will result to The General Tire & Rubber Company.

5. Specifically, in our Industrial Products and Chemical/Plastics divisions, solvents containing trace amounts of benzene are used in many hand-contact operations. These include, but are not limited to: polyester and styrene unloading and transfer; parts and reactor cleaning; roll coating; printing operations; and, manufacture and use of solvent-based adhesives.

6. We have been informed by our suppliers that it is virtually impossible to remove all traces of benzene from commercial solvents used by our industry.

7. Compliance with the present Standard would require such equipment as imeprvious gloves, respirators and eyeglasses. The net effect would make it impossible to assemble tennis balls, assemble bushings and mold gaskets. These are precision operations which necessitate direct hand contact.

8. In my review of the Benzene Standard, I have given special consideration to 29 CFR Section 1910.1028(k)(2), which provides for labeling requirements. This provision requires that caution labels be affixed to all containers of benzene and of products containing any amount of benzene. If General Tire is required to abide by the letter of this section, irreparable harm will result.

9. Because of the severe requirements, it is impossible to comply with such labeling requirements within the stipulated time period. If taken to its logical conclusion, we could be required to label all products in our work environment which could contain mere traces of benzene contaminates in their solid form such as latex materials, coated vinyl fabrics and rubber products being shipped out for sale. It is our belief that this aspect of the Standard exceeds the authority of OSHA.

10. I further state that the above matters are based upon my personal knowledg or upon information supplied to me by competent and knowledgeable persons upon whom I rely, and are true to the best of my knowledge and belief.

/s/ Roy N. Johnson
ROY N. JOHNSON.

[Amend. Exh. 32-F-3]

* * * *

SUPPLEMENTARY AFFIDAVIT
OF JAMES R. SANKEY OF
THE GOODYEAR TIRE & RUBBER COMPANY
IN SUPPORT OF MOTION FOR STAY

STATE OF OHIO)
) ss.
COUNTY OF SUMMIT)

JAMES R. SANKEY, being duly sworn, deposes and says:

1. I am now and have been for the past three years Director of Domestic Tire Production for The Goodyear Tire & Rubber Company ("Goodyear"), an Ohio corporation with its principal offices located in Akron, Ohio. I have been employed by Goodyear for thirty five (35) years in various capacities relating to the manufacture of tires for automobiles, trucks and other wheeled vehicles and have managed tire plants in Akron, Ohio; Union City, Tennessee; and New Delhi, India. I am personally familiar with all aspects of the process of manufacturing automobile, truck and related type tires.

2. Goodyear is the world's largest manufacturer of tires and produces more tires in the United States than any other tire producer.

3. As Director of Domestic Tire Production, I am directly responsible for the operations of eight (8) domestic tire manufacturing plants owned and operated by Goodyear. These facilities are located in Akron, Ohio; Danville, Virginia; Gadsden, Alabama; Jackson, Michigan; Los Angeles, California; Madisonville, Kentucky; Topeka, Kansas; and Union City, Tennessee. Collectively, these facilities employ more than 15,695 persons in manufacturing and related operations. I am personally familiar with all aspects of the operations at each of these facilities.

4. I have read and am familiar with the permanent standard of the Occupational Safety and Health Administration for the regulation of occupational exposure to benzene (29 CFR 1910.1028, 43 *Fed Reg* 5917, Feb 10, 1978) (the "Benzene Standard"). I have particularly reviewed the sections of the Benzene Standard dealing with dermal and eye contact with liquid benzene, 29 CFR 1910.1028(c)(2) and (h) (collectively referred to as the "Dermal Contact Sections"). I am also familiar with OSHA's announced intention to stay enforcement of the Benzene Standard where the sole exposure is from mixtures containing 0.1% or less of benzene.

5. Even if the Benzene Standard's application is thus restricted, Goodyear is unable to manufacture tires in compliance with the Dermal Contact Sections of the standard, and Goodyear will, therefore, suffer irreparable harm if the Dermal Contact Sections of the Benzene Standard are not stayed.

6. As stated in my prior Affidavit, dated March 8, 1978, the use of petroleum solvents is essential to the manufacture of tires. As described fully in my first Affidavit, the tire building process necessarily involves manual contact by the builder with the surface of the tire which has been activated by solvents containing benzene. This manual contact involves dermal contact, since gloves or other protective hand coverings are neither suitable nor feasible in tire building.

7. The petroleum solvents suitable for tire building contain trace amounts of benzene as an impurity. Goodyear has requested all major suppliers of petroleum solvents to provide Goodyear with solvents which do not contain any amount of benzene. These suppliers have advised Goodyear that it is not feasible to remove all the benzene from petroleum solvents used in the construction of tires. Also, despite Goodyear's requests, solvent suppliers have refused to assure or guarantee any fixed, low levels of benzene content. Therefore, Goodyear is unable to assure itself that it will receive solvents containing 0.1% or less of benzene.

8. Therefore, Goodyear cannot comply with the Dermal Contact Sections of the Benzene Standard, even if OSHA proceeds to stay enforcement of the standard as to exposures solely from mixtures containing 0.1% or less of benzene. Goodyear will suffer irreparable injury if the Dermal Contact Sections are not stayed, in that Goodyear's domestic tire production will be brought to a virtual standstill.

9. The Kelly-Springfield Tire Company ("Kelly-Springfield") and Lee Tire & Rubber Company ("Lee") are wholly-owned subsidiaries of Goodyear which are engaged in the manufacture and sale of tires and which employ more than 9,395 persons in manufacturing and related operations. On information and belief, compliance with the Dermal Contact Sections and Labeling Sections of the Benzene Standard by Kelly-Springfield and Lee would bring tire production at Kelly-Springfield and Lee to a standstill.

10. On information and belief, there are several other areas of Goodyear's tire and rubber products manufacturing where Goodyear will be severely and irreparably harmed if the Dermal Contact Sections are not stayed. Among them are the building of motorcycle tires, v-belts, conveyor belts and hosing, all of which operations involve the use of rubber solvents as tackifying agents in the building process and which will involve some degree of dermal contact with such benzene-containing solvents. These operations are conducted in six (6) domestic plants.

11. I further state that the above matters are based upon my personal knowledge except where otherwise noted, in which case they are based upon information and belief.

Dated this 28th day of March, 1978.

/s/ James R. Sankey
JAMES R. SANKEY

[AMEND. EXH. 32-F-3]

* * * *

AFFIDAVIT OF ROBERT W. LAUNDRIE OF THE GENERAL TIRE & RUBBER COMPANY IN SUPPORT OF MOTION FOR STAY

Rcbert W. Laundrie, being duly sworn, deposes and says:

1. I am now, and have been since 1971, Manager of Ecology, Safety & Health Engineering for the Chemical/Plastics Division of the General Tire & Rubber Company ("General"), an Ohio Corporation having its principal place of business located in Akron, Ohio. I have been employed by General for 22 years in various capacities in the chemical and plastics industry, and I am personally familiar with all phases of that Division's manufacturing operations, including the operations involved in the manufacture of tennis balls.

2. The General Tire & Rubber Company is the largest producer of tennis balls in the United States, with domestic manufacturing plants located in Phoenix, Arizona and Jonesboro, Arkansas, and with total employment at both locations being approximately 500 persons.

3. I have read and I am familiar with the Occupational Safety and Health Administration's permanent standard for regulation of exposure to benzene in the work place (29 CFR 1910.1028). I have reviewed the standards and believe that compliance with most provisions, while difficult, will be attainable.

4. I have specific concern, however, with the requirement of the standard respecting dermal and eye exposure to liquids containing benzene (29 CFR 1910.1028(c)(2)), as those standards relate to the manufacture of tennis balls. I am also familiar with OSHA's announced intention to consider modification of the standard so that it would be applicable to only liquids containing greater than .1% benzene by volume. I am, however, informed and personally believe that as this provision is presently written, The General Tire & Rubber Company will be

unable to continue to manufacture tennis balls, and at the same time, comply with the above regulations. In addition, this situation will not be improved by OSHA's proposed amendment, and in either case, General will suffer irreparable harm.

5. Petroleum-based solvents are essential to the tennis ball manufacturing industry, as they are a necessary ingredient in the cement mixtures used to assemble the various tennis ball's components. Benzene is not a necessary element in tennis ball manufacture, but it exists in trace amounts as a contaminant in the petroleum-based solvents presently available to our manufacturing plants.

6. Though efforts have been made to obtain a reliable source of benzene-free solvents, our suppliers are not presently able to supply solvents in a benzene-free state, or if available, not presently able to supply our production needs of approximately 19,000 gallons per month on a repetitive basis, totally benzene-free.

7. Solvent suppliers presently serving our tennis ball manufacturing facilities advise that they can deliver solvents containing .3% to .5% benzene on a repetitive basis, in sufficient quantities to meet production requirements.

8. Solvents presently available in sufficient quantities to maintain production at our tennis ball facilities cannot meet either the present or proposed OSHA standards for benzene content.

9. While most of the tennis ball production process is highly automated, a certain amount of hand transfer is required, and a potential for skin contact with wet cements containing trace amounts of benzene exists during these transfer operations.

10. Due to the tacky conditions of the components, and their thin and flexible condition, accurate and efficient handling cannot be accomplished wearing heavy gloves, and no known thin rubber gloves are currently available that would not react adversely with the wet rubber cements or adhesives. While we are presently exploring the availability of barrier creams or other directly applied solutions that might protect against

such exposures, none are presently known to be effective; and further time for analysis and experimentation will be necessary in this area.

11. While a possible exposure to trace amounts of benzene does exist, the exposure potential appears to be limited to approximately 40 to 45 employees out of our entire operations. A review of available medical records from 1976 to present reveals only one reported skin disorder which may or may not have arisen as a result of contact with cements containing benzene; and therefore, no apparent dermatitis hazard is known to result from these potential exposures.

12. For the foregoing reasons, General will be unable to comply with either the present or proposed OSHA standards for skin contact with liquids containing benzene, and still continue tennis ball manufacturing operations. While solutions to these problems are no doubt available in the future, our present technology will not permit compliance and production to co-exist; and therefore, in the absence of a stay of the standard, General will suffer irreparable harm.

13. I further state that the above matters are based upon my personal knowledge, or upon information supplied to me by competent and knowledgeable persons upon whom I rely, and are true to the best of my knowledge and belief.

/s/ Robert W. Laundrie
ROBERT W. LAUNDRIE

* * * *

[Amend. Exh. 32-A-3]

IN THE UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

Nos. 78-1257, 78-1253, 78-1486, 78-1676, 78-1677

AMERICAN PETROLEUM INSTITUTE, ET AL., PETITIONERS,

v.

OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION; UNITED STATES DEPARTMENT OF LABOR; DR. EULA BINGHAM, ASSISTANT SECRETARY OF LABOR; AND RAY MARSHALL, SECRETARY OF LABOR, RESPONDENTS,

INDUSTRIAL UNION DEPARTMENT, INTERVENOR.

SECRETARY OF LABOR'S SUPPLEMENTAL OPPOSITION TO PETITIONERS REQUEST FOR STAY PENDING JUDICIAL REVIEW

* * * *

[67] In like fashion, various rubber manufacturers have appeared here, arguing that they cannot comply with the personal protective equipment sections of the standard absent the 1% exemption because the manufacture of tires requires the application of solvents containing benzene by hand, and rubber gloves cannot be used because they become tacky. These petitioners also participated in the rulemaking proceeding with full knowledge that within one year at best the agency was proposing to include these solvents in the standard. Yet their problem with personal protective equipment compliance raised here was never raised before the agency. Like Chemical Specialties, it is disingenuous, to say the least, for these companies now to come into court and seek relief for the results of their own inaction. As indicated in the agency's response to their petition for administrative review, it appears that they have, even though at a very late date,

advanced a real problem which is probably appropriately dealt with through the temporary variance procedure dealt with *infra* at 64-65. Again, an employer may always prove that it is simply impossible for him to comply with a standard in the context of an enforcement proceeding and, as is the case with Chemical Specialties, to the extent citations do issue, an employer's good faith attempts to comply will of course mitigate any penalty which might be proposed.

[Amend. Exh. 32-F-4]

* * * *

AFFIDAVIT OF N. A. DAIGLE
OF THE FIRESTONE TIRE & RUBBER COMPANY
IN SUPPORT OF MOTION FOR STAY

STATE OF OHIO)
) SS
COUNTY OF SUMMIT)

I, N. A. Daigle, being duly sworn, upon oath depose and state as follows:

1. I am currently employed by The Firestone Tire & Rubber Company ("Firestone") as Manager of North American Tire Plant Laboratories at Firestone's corporate headquarters in Akron, Ohio.

2. The statements of fact set forth herein are true and correct to the best of my knowledge, information and belief.

3. Firestone has conducted preliminary tests to determine the effect on adhesion from the use of barrier creams in tire building operations to prevent any possible absorption of benzene through the skin. Firestone has no actual knowledge of the protection provided by such creams, but Firestone tested the barrier cream product reported to provide the best protection against possible absorption of benzene through the skin.

4. Tests were conducted by applying this cream to the hands, working the cream into the hands by rubbing, wiping off the excess cream with a dry cloth, and then handling the surface of tire stock with the finger tips. A standard one inch adhesion pad was prepared to determine the effect on adhesion from this use of this barrier cream. These test results indicate a 60% loss of adhesion when the cream was applied in the above manner.

5. Additional tests were conducted applying this cream directly to the surface of the tire stock. This condition

could occasionally occur in tire building, particularly from an individual not removing an excess of cream before handling the surface. A standard one inch adhesion pad was prepared to determine the effect on adhesion from this use of this barrier cream. Such tests indicated a 100% loss of adhesion.

6. Adhesion is essential in the tire building process and a 60% loss of adhesion is entirely unacceptable. Such a loss of adhesion would result in tire separation and an unsafe tire.

/s/ N. A. Daigle
N. A. DAIGLE

* * * *

SECOND SUPPLEMENTAL AFFIDAVIT OF ROGER W. STRASSBURG OF THE B. F. GOODRICH COMPANY IN SUPPORT OF MOTION FOR STAY OF OSHA'S PERMANENT BENZENE STANDARD

STATE OF OHIO)
) SS.
COUNTY OF SUMMIT)

I, ROGER W. STRASSBURG, being duly sworn, do hereby state as follows:

1. On March 8, 1978, I executed for this proceeding an Affidavit in Support of Motion to Stay and on March 29, 1978, I executed a Supplemental Affidavit in Support of Motion to Stay.

2. Paragraph 13 of my March 8 Affidavit and paragraph 3 of my Supplemental Affidavit show the practical impossibility of building tires using necessary benzene-containing rubber solvent while protecting the tire builders' hands with gloves. Since the date of my Supplemental Affidavit I have received a Technical Document from the Goodrich Tire Division reporting on the tests conducted on "Use of Gloves During Tire Construction" with which was enclosed a copy of an article from the February, 1978 issue of the American Industrial Hygiene Association Journal authored by Sansone and Tewari entitled "The Permeability of Laboratory Gloves to Selected Solvents". These documents are attached hereto as Exhibits A and B respectively. From these documents it is apparent that there are no available gloves which are satisfactory for use by tire builders to prevent skin contact with the rubber solvent. The only glove material not permeable to benzene containing solvent is polyvinyl alcohol (PVA) and it is permeable to water (see last column of last line of Table 1 of Exhibit B). Hence PVA gloves would be attacked from the inside by the water from the "hand sweating" which always occurred.

3. In paragraph 14 of my March 8 Affidavit I pointed out that the preamble to the Benzene Standard states that the *primary* cause of entry of benzene in man is through inhalation; that the Standard provides a permissible exposure limit (PEL) of airborne inhalable benzene of 1 ppm TWA over 8 hours (twice the "action level") for this *primary* mode of entry and that the Standard provided nothing akin to an "action level" or PEL with respect to a *possible* secondary mode of entry of benzene in man through skin absorption. In paragraph 5 of my Supplemental Affidavit I pointed out that the existing literature on benzene absorption through the skin related only to liquid benzene (i.e., essentially 100% benzene) not to liquid mixtures containing small amounts of benzene (rubber solvent with 0.1% up to 1% benzene). These considerations, coupled with the recent OSHA proposed exclusion of liquid mixtures containing 0.1% or less benzene, have led me first to seek to determine the relationship between entry of benzene in man through inhalation of airborne benzene at the PEL versus *absolute maximum possible entry through skin absorption* from a 0.1% benzene solvent and secondly to seek to determine the maximum *probable entry by skin absorption* from rubber solvent using the existing literature as to entry by skin absorption from essentially 100% benzene. I have made such determinations as accurately as I can in the limited time available and the results are set forth below.

4. Considering first entry of benzene in man through inhalation, I find from the reference book "Industrial Hygiene and Toxicology" by Patty, Vol. 1, 2nd Edition, page 151, that a worker engaged in moderately heavy work (typical of a tire builder) will breath in 9600 liters of air in an 8 hour working day. If this air contains the PEL of 1 ppm of benzene, that is 3 mg per m^3, the total amount of benzene entry is 9.6 x 3 or 28.8 mg over the 8 hour period.

5. Consider now the absolute maximum possible entry of benzene by skin absorption in respect to a tire builder's use of 0.1% benzene rubber solvent. A tire builder engaged in applying the "first step tread over sidewall", a

typical tire building operation using rubber solvent, will in an 8 hour day have the palm of one hand in the rubber solvent approximately 30 times. If the whole hand is dipped in rubber solvent, 2.64 grams of solvent will remain on the hand after the dip, as determined by accurately weighing a container of solvent before and after the dip. Thus, the *absolute maximum possible* amount of benzene which could enter the tire builder from the solvent in an 8 hour day is 2.64 divided by two (the palm being one-half of the whole hand) times 0.001 (0.1% benzene in solvent) times 30 which equals 39.6 mg benzene.

6. From paragraphs 4 and 5 above, it is apparent that total entry of benzene into the body of a tire builder through skin absorption would be of the same magnitude as total entry of benzene through inhalation at the PEL even if *it be assumed that absolutely all the benzene contacted by the hands were absorbed.* This assumption is obviously false since it takes no account whatever of the fact that the bulk of benzene containing-solvent in contact with the worker's hand is continuously and rapidly being evaporated so that only a small portion of the total benzene which originally contacts the hands could possibly be absorbed through the skin. This leads to a calculation of the *probable maximum* entry through absorption of benzene in rubber solvent based on the existing literature as to absorption from essentially 100% benzene.

7. The article by Hanke, Dutkiewicz and Piotrowski entitled "Absorption of Benzene Through the Skin in Man" appearing in the Institute of Industrial Toxicology of the Institute of Labor Health, Lodz, Poland, of record in the proceeding leading to the Benzene Standard, describes experiments on determination of maximum actual absorption of benzene in man as a result of direct contact with essentially 100% liquid benzene. The statement is made (p. 16 of translation for OSHA) that for an area of both palms of man's hands of 600 cm^2, the maximum amount of *actual* benzene absorption in the course of 8 hours "*might be about 2000 mg*". Relating 2000 mg with both palms in 100% benzene to one palm in 0.1% benzene, the value for *maximum actual benzene absorption* by tire builder's use of rubber solvent with 0.1% benzene would be, on a linear basis, 0.001 x 2000 mg divided by 2 or only 1 mg as against the *maximum possible benzene absorption* from paragraph 5 above of approximately 40 mg. On the same linear basis, if rubber solvent containing 1% benzene were used, maximum actual benzene absorption from skin contact would be 10 mg and this value is still only one-third of the approximately 30 mg from inhalation at the PEL.

8. I recognize that I have no scientific information to establish the linear relationship basis in my calculations in paragraph 7. However, in the light of the testimony of Dr. Howard Maibach at the OSHA hearings to the effect that the Hanke, et al experiments, through use of the glass plate, had *driven the benzene through the skin* to a much greater degree than would otherwise have been the case, I believe that any "under-estimation" due to my using the linear relationship is counterbalanced by the "over-estimation" inherent in the Hanke, et al study.

9. I conclude from the above that there would be no more actual absorption of benzene as a result of the skin contact involved in the tire building operation through use of rubber solvent containing up to 1% benzene than from inhalation of benzene at the PEL or even at the "action level". I further believe that insofar as it applies to skin contact in tire building operation the OSHA proposed "exemption" from the Benzene Standard of liquids containing 0.1% or less benzene could logically be applied to liquids containing more than 0.1% benzene up to even as much as 1% benzene, without harm to the health of tire builders.

10. I am aware that OSHA considers various skin conditions such as dermatitis, also to be a factor with respect to the dermal contact portions of the Benzene Standard. However, I believe it is well known that such conditions are by no means unique to benzene and apply equally to other hydrocarbons which dissolve "fats" and that, therefore, they are not properly a factor for consideration in fixing the percentage of benzene in liquid mixtures which

should be exempted from the dermal contact provisions of the Benzene Standard.

/s/ Roger W. Strassburg
ROGER W. STRASSBURG

[The following is the percentage-exclusion amendment and the accompanying statement of reasons, 93 Fed. Reg. 27962 (June 27, 1978)]

Title 29—Labor

CHAPTER XVII—OCCUPATIONAL SAFETY AND HEALTH ADMINISTRATION, DEPARTMENT OF LABOR

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

Occupational Exposure to Benzene; Liquid Mixtures

AGENCY: The Occupational Safety and Health Administration, Department of Labor.

ACTION: Final rule.

SUMMARY: This document amends the recently issued occupational safety and health standard for exposure to benzene by: (1) Exempting from all the provisions of the permanent standard for benzene (29 CFR 1910.1028), for the first three years following the effective date of this amendment, liquid mixtures containing 0.5 percent or less benzene, and thereafter liquid mixtures containing 0.1 percent or less benzene; and (2) exempting from the labeling requirements liquid mixtures containing benzene which are already packaged and which contain 5.0 percent or less benzene. The amendments are in response to several petitions concerning the applicability of the benzene standard to liquid mixtures.

EFFECTIVE DATE: June 27, 1978.

FOR FURTHER INFORMATION CONTACT:

Mr. Gail Brinkerhoff, Office of Compliance Programs, OSHA, Third Street and Constitution Avenue NW., Room N3112, Washington, D.C. 20210, telephone 202-523-8034.

SUPPLEMENTARY INFORMATION: These amendments are issued pursuant to sections 4(b) and 6(b) of the Occupational Safety and Health Act of 1970 (the Act) (84 Stat. 1592, 1593; 29 U.S.C. 653, 655), the Secretary of Labor's Order No. 8-76 (41 FR 25059) and 29 CFR Part 1911. These amendments appear at 29 CFR 1910.1028(a)(2)(iii) and at 29 CFR 1910.1028(k)(2)(iii).

I. Background

Benzene is a naturally occurring constitutent of crude oil and national gas produced from underground reservoirs and surfacing through wells. There are approximately 630,000 wells in some 10,000 oil and gas fields in the U.S. (exhibit 29D1). One or more reservoirs underlies each of these oil and gas fields (exhibit 29f, p. 2). Since crude oil and natural gas vary in composition and physical properties from reservoir to reservoir (exhibit 29f, p. 2), the benzene content of the fluid at a particular oil or gas field may vary from well to well.

From the wellhead, the reservoir fluid is delivered by flow lines or gathering lines to separation facilities (exhibit 29D1) or field treatment plants (exhibit 29f, p. 4) where it undergoes a number of production treatment steps necessary to produce marketable crude oil, condensates and natural gas streams, as well as a variety of hydrocarbons (exhibit 29f, p. 4).

The benzene content of crude oil ranges from below detectable limits to greater than 1 percent (exhibit 29f, p. 3). Condensates produced from natural gas liquids present in both crude oil and natural gas (exhibit 29f, pp. 2-3) have a higher percentage of benzene than crude, with that percentage ranging from approximately 0.2 to 1.0 percent by volume (exhibit 29D1). The benzene in natural gas varies from 0 to about 4 percent (exhibit 29D1).

From the separation facilities or treatment plants, the crude oil, condensates and liquid and gaseous hydrocarbons are delivered to refineries either by waterway or by pipelines (exhibit 29D1; Comeaux). It is common practice for liquids from a number of fields to be combined

into one pipeline stream for transportation do refineries (exhibit 29D1); Comeaux, p. 4).

At the refineries, the crude oil and field condensate liquids are stored in holding tanks prior to processing (exhibit 29f, p. 5). Typical petroleum refining processes are many. Not all refineries have all of these processes since there is specialization, such as fuels, lubes or petrochemical operations, within refineries (exhibit 29f, p. 5). At all refineries, however, additional benzene is generated during refining by catalytic cracker, reformer and coker operations (exhibit 29f, p. 2; tr. 284).

Petroleum refined products are many and their benzene content varies according to the content of the crude taken into the refinery, the nature or the efficiency of the refining process, and the balance of product demands on the refinery. Thus, the benzene content of product streams within a single company may vary from refinery to refinery or within a single refinery from year to year. The same product from different refineries or at different times from the same refinery, consequently, may have a different benzene content (tr. 284-5). Motor gasoline ranges from 1 to 3 percent benzene by volume (Bailey). Aviation gasoline, specialty naptha solvents and naptha-based, (type B) jet fuels may exceed 1 percent benzene concentrations. Heavier jet fuel (type A), light fuel oils and cutback asphalts may occasionally exceed 0.01 percent benzene. Petrochemical feedstock napthas and certain aromatics, such as toluene may contain up to 1 percent benzene (exhibit 29f, pp. 7-8). This petrochemical feedstock is used to produce ethylbenzene, styrene monomer, cumene, phenol, cyclohexane, and nitrobenzene.

Processed refined petroleum products are distributed through marketing channels, including bulk terminals and bulk plants, to consumers. Initial distribution from the refinery storage facilities may be by pipeline, barge, marine tankers, tank truck or tank car (exhibit 29f, p. 11). These refined products have numerous uses, such as fuels, extractants, processing aids, and solvents in paints, surface coatings, adhesives and pesticides, inks, etc. The benzene content of these products varies from less than

one-tenth to a few percent (tr. 284, comment 53, 58, 21, 35).

There are some substitutes for benzene; however, most of the solvent substitutes themselves contain benzene. As indicated below, the percentage of benzene in some substitutes may range up to 4 percent (18-45; tr. 304).

Benzene is also derived from coal. Recovery of coal-derived benzene, primarily as a by-product of the coking process in steel mills, accounts, however, for only 6 percent of the total U.S. production (43 FR 5918). The light oil, which is condensed from coke gases, contains up to 70 percent benzene. This light oil is distilled to produce benzene. Most light oil plants do not produce benzene but sell their light oil to petroleum refineries for further processing. Only 10 light oil plants do produce benzene and these sell it to other users.

II. History of Regulation

On February 10, 1978, a permanent occupational safety and health standard regulating occupational exposure to benzene was published in the Federal Register (43 FR 5918) as 29 CFR 1910.1028. (A correction document was published on March 31, 1978, at 43 FR 13561). This standard required employers to take prescribed measures to control employee exposure to benzene. The standard applied to each place of employment where benzene in any quantity was produced, reacted, released, packaged, repackaged, stored, transported, handled or used. The standard contained no percentage exclusion and applied to work operations involving any amount of benzene.

The permanent benzene standard was developed, pursuant to sections 6(b) and 6(c) of the act, after exhaustive rulemaking which commenced with publication on May 3, 1977 of an Emergency Temporary Standard for Occupational Exposure to Benzene (42 FR 22516). The emergency temporary standard exempted liquid mixtures containing 1 percent or less of benzene volume, or the vapors released from these liquids. On May 27, 1977, OSHA published a proposed permanent standard to control occupational exposure to benzene (42 FR 27452).

This proposed standard would also have exempted work operations where the only exposure to benzene was from liquid mixtures containing 1.0 percent (0.1 percent after 1 year) or less of benzene by volume, or the vapors released from these liquids. On the basis of the record developed in the rulemaking on the permanent benzene standard (Docket H-059), OSHA concluded that there was no consistent predictable relationship shown between the percentage of benzene in a liquid mixture and the resultant airborne exposure to benzene and that, consequently, the percentage proposed exclusion could not be supported (43 FR 5942).

After promulgation of the final standard which contained no percentage exclusion, OSHA received requests from several employers and employer groups for an administrative stay of the standard or other relief from the provisions of the standard as it applied to work operations where exposure to benzene resulted from liquid mixtures containing small or "trace" amounts of benzene. For reasons set forth in its notice (43 FR 12890, March 28, 1978), OSHA proposed to amend the benzene standard to exclude from its coverage work operations where exposure to benzene is from liquid mixtures containing 0.1 percent or less benzene or the vapors from such liquids. Skin contact with such mixtures would also be excluded from the standard. Pending final action on this proposed amendment, OSHA stayed the application of the provisions of the benzene standard to such work operations (43 FR 12891). Since this stay was immediately effective, OSHA commenced an expedited rulemaking to resolve the percentage exclusion question so that employers could know which, if any, of their operations were excluded from the permanent benzene standard. (A correction document was published on April 4, 1978, at 43 FR 14071). On April 28, 1978, OSHA published a notice of hearing on the proposed amendment (43 FR 18215). The public hearing on this proposal was held on May 23 and May 24 at Washington, D.C. Approximately 40 individuals participated at this hearing. Furthermore, more than 100 comments, arguments, and views were received from interested parties. The verbatim transcript of this hear-

ing, as well as the numerous comments, exhibits, and briefs submitted to OSHA before, during and after the hearing, are part of this rulemaking record, along with portions of the record in the earlier benzene proceeding which were relevant to the issues herein. The rulemaking record was originally scheduled to close on June 8, 1978, but, at the request of participants, was kept open until June 12, 1978.

These amendments are based on a careful consideration of the entire record of the informal rulemaking hearing, including the transcript, exhibits, and prehearing and post-hearing written comments. Copies of the official list of hearing exhibits, comments, and notices of intent to appear at the hearing can be obtained from the Docket Office, Docket H-059A, Room S6212, U.S. Department of Labor, 3rd Street and Constitution Avenue N.W., Washington, D.C. 20210.

III. Regulatory Analysis and Environmental Impact

Since an economic impact statement for the permanent standard (43 FR 5918) was prepared by OSHA pursuant to Executive Orders 11821 and 11949, OSHA has not performed a separate regulatory analysis pursuant to Executive Order 12044 (43 FR 12661, March 24, 1978). The economic analysis for the permanent standard considered the economic impact of compliance on employers with operations utilizing liquid mixtures containing any amount of benzene (43 FR 5934-5941). This amendment exempts from the permanent standard operations utilizing 0.5 percent or less benzene (0.1 percent or less after 3 years) and, therefore, reduces the cost of compliance with the standard.

In view of the fact that the amended standard does not require that employers reduce the amount of benzene in their products, costs involved in reducing the percentage of benzene in liquid mixtures in order to avoid coverage by this standard have not been attributed to the amended standard.

The final environmental impact statement published January 1978, prior to the issuance of the permanent benzene standard concluded that the standard would have a beneficial impact on the workplace environment and also that beneficial effects on the environment external to the workplace may also be anticipated. This amendment to the permanent benzene standard may result in employers switching to other solvents (containing lower benzene contamination levels). However, the atmospheric impact of such action is not expected to be significant. Where reformulation is accomplished to reduce organic solvent usage, the atmosphere will realize a reduction in total hydrocarbon load. As these types of actions were addressed in the final environmental impact statement, this amendment is not expected to alter the basic conclusions contained in that document. Accordingly, it was concluded that no new environmental impact statement was necessary for this amendment.

IV. Principal Issues Involved

The following is a discussion of the major issues involved in the rulemaking on the proposed percentage exclusion and an analysis of the evidence submitted into the record. The exhibit numbers refer to the certified exhibit list of docket H-059A. The first number designates the particular exhibit on that list. Where the exhibit contains more than one item, the second number references the particular item of the exhibit. The designation "tr." refers to the transcript of the hearing on percentage exclusion and indicates the pages of that transcript which are referenced. Furthermore, the designation "PC" refers to post hearing comments submitted by interested parties. All references are intended to provide examples of record support for the information stated.

(1) WHETHER WORK OPERATIONS SHOULD BE EXEMPT FROM § 1910.1028 WHERE THE SOLE OCCUPATIONAL EXPOSURE TO BENZENE IS FROM LIQUID MIXTURES CONTAINING LESS THAN A SPECIFIED PERCENTAGE OF BENZENE

The majority of those responding recommended that the benzene standard be amended to exclude from its coverage liquid mixtures containing less than a specified percentage of benzene. Reasons in support of this form of exemption varied. Some participants argued that exposure to low levels of benzene does not result in any health hazard, particularly leukemia (tr. 225, 391, 313, and exhibits 18-34, 63, 77, 84, 91). Other participants pointed out that they do not add benzene to their products but that benzene is an unavoidable contaminant in all petroleum based products (tr. 68, 78, 88, 106, 107, 120, 129, 132, 163, 168, 187, 215, and exhibits 18-41, 93, PC-5-8). Oil and gas producers stressed that benzene is a natural contaminant of crude oil and gas and that it is technologically infeasible to remove benzene at the wells (exhibits 18-77, 85, 1, 19). Refiners contended that it is economically prohibitive to remove benzene from their process streams, particularly within a short timeframe (exhibit 18-48). Most industry participants presented data indicating that the low levels of benzene in the liquid mixtures present in their workplaces produced airborne concentrations below the standard's permissible exposure limit of 1 ppm. (This data is discussed below under issue 6.)

Objections to any percentage exclusion for airborne exposure were raised by the Oil, Chemical & Atomic Workers (tr. 400). OCAW argued that, even where low percentages of benzene were present in liquid streams, refinery process units were subject to frequent leaks resulting in employee exposures above 1 ppm. OCAW contended that only where process units are well maintained, can exposures be reduced to the permissible exposure limit, but that such high quality maintenance cannot be guaranteed (tr. 402).

The United Rubber, Cork, Linoleum & Plastic Workers of America (URW) contended by way of comment that

while reduction of the amount of benzene in a liquid can result in reduction of airborne concentrations to conform with a PEL of 1 ppm, reduced levels cannot be attained in certain processes unless ventilation control is provided. URW also objected to permitting dermal contact with benzene mixtures where there has been no documentation of a "no-risk" health factor to benzene on skin contact, and recommended that temporary variances be sought by industry in situations where the use of protective clothing is a problem (exhibit 18-33).

The Public Citizen Health Research Group opposes the proposed amendment on the grounds that there is no safe level for exposure to a carcinogen and that liquid mixtures containing 0.1 percent benzene have been shown to give rise to exposure levels in excess of the PEL of 1 ppm (exhibit 18-94).

For different reasons, the American Petroleum Institute also urged that a percentage exclusion not be adopted, other than possibly for dermal exposure. API's objections to a percentage exclusion were based on the view that the medium or matrix in which benzene is found, the environmental conditions of temperature, humidity, air movement, and physical volume of space, the physical nature of the system in which benzene is found—namely whether in a closed or open system, and work practices are all critical to reduction of benzene exposure. In lieu of a percentage exclusion, API proposed that OSHA limit the scope of the benzene standard by adopting appropriate triggering mechanisms for activation of individual provisions of the standard. Thus, initial monitoring of airborne exposures should occur, in API's view, only when professionals, acting for the employer, have reason to believe that employee exposure is above the level which triggers the monitoring requirement (tr. 353).

Dr. Hervey B. Elkins testified on behalf of AISI that a percentage exemption would be appropriate inasmuch as naturally occurring benzene is found as a contaminant in many liquids employed in industry, formulation of many products will involve ingredients which often contain benzene in small quantities, and many products are made by chemical reactions employing benzene as a raw

material. Dr. Elkins indicated that to completely eliminate the last traces of benzene from these materials may be very difficult (PC 82).

(2) WHETHER 0.1 PERCENT BENZENE IS THE APPROPRIATE PERCENTAGE FOR EXEMPTION, OR WHETHER THE PERCENTAGE FIGURE SHOULD BE HIGHER OR LOWER

Some participants supporting a percentage exemption indicated that 0.1 percent would be of no significant benefit to them since the benzene contaminated mixtures they used contained benzene in excess of that figure. They also argued that a higher percentage exemption would be appropriate since the airborne concentrations arising from the higher benzene content mixtures did not generally exceed 1 ppm.

Further, industry participants provided evidence that, at present, many suppliers cannot furnish the various benzene-contaminated materials used in their processes with a benzene content as low as 0.1 percent. (This evidence is discussed in detail in issue 5.) For example, tire manufacturers testified that the rubber solvents used in tire building could not be obtained with any confidence that the benzene content would not be up to at least 0.7 percent. They maintained, therefore, that a percentage exemption of at least 0.7 percent would be appropriate, especially to provide relief from the requirement for protective clothing which is infeasible in these operations (tr. 68, 87, 108, 170, 188, 212, 215).

The Adhesives & Sealant Council (tr. 224), Wilhold Glues (tr. 224), St. Clair Rubber Co. (tr. 260), Miracle Adhesive Corp. (tr. 268), DuPont (tr. 313), the American Iron & Steel Institute (tr. 396), and others (exhibits 18-16, 21, 61, 53, 55, 56, 45, 108) suggested that, because of the unavailability of low benzene solvents and the lack of potential for exposure above 1 ppm, that a 1.0 percent exemption would be appropriate. The B. F. Goodrich Co. indicated that while they would be willing to comply with a 0.1 percent exemption as it would apply to generation of airborne concentrations, a special action level of 0.5

percent for activation of dermal protection requirements would be necessary for them to be able to comply with the standard. Other participants argued that 0.1 percent is inappropriate since exposures below 1 ppm occur in such operations as oil and gas production with crude oil and gas liquids containing up to 4 percent benzene (exhibit 18-71, PC 81).

Industry participants endorsing a 0.1 percent exclusion did so primarily because the benzene containing materials used in their operations generally contained less than 0.1 percent benzene and they would thus be exempt from the standard (exhibits 18-29, 37, 46, 70, 89, 106, 107).

Dr. Hervey Elkins testified that, while it may not be possible to establish liquid percentage limits that will guarantee, with complete certainty in every possible situation, airborne concentrations that will not exceed a specified level, it would be logical and appropriate to accept a particular percentage exemption which would most likely, based on calculations of available data, be consistent with a permissible exposure limit of 1 ppm. The calculations provided by Dr. Elkins were based on theoretical considerations, and on extrapolation from data in papers written by him. The mean of all values of benzene percentage limits in liquid mixtures consistent with a permissible exposure level of 1 ppm was calculated by Dr. Elkins to be 0.5 percent (PC 82).

(3) WHAT IS THE CURRENT PERCENTAGE (OR RANGE OF PERCENTAGES) OF BENZENE IN LIQUID PRODUCTS, SUCH AS PRINTING INKS, PETROLEUM SOLVENTS SUITABLE FOR TIRE BUILDING, ADHESIVES, SEALANTS, PAINTS, COATINGS, DETERGENTS, INSECTICIDES, DISINFECTANTS, WAXES, FLOOR FINISHES, CRUDE OIL, PETROLEUM SOLVENTS OF VARYING GRADES, GAS LIQUIDS, LUBRICATING OILS, PETROCHEMICALS, GASOLINE IN REFINERY STREAMS, AND SIMILAR PRODUCTS

Participants who furnished information on this issue generally indicated that, since benzene is primarily a contaminant rather than an intended final ingredient, the

benzene content of liquid products would vary not only from supplier to supplier but also from the same supplier. The American Petroleum Institute has indicated that production factors, which cause varying benzene content in their products, include differences in crude runs, the nature and efficiency of individual refinery process and the specific balance of final products produced at any point in time (PC 104).

Tire manufacturers reported rubber solvents used in tire building as containing up to 1.0 percent benzene, with only one supplier claiming capability of supplying solvents with 0.1 percent benzene or less. However, industry analysis of that company's shipments indicated benzene content from 0.097 to 0.137 percent (tr. 88, 95, exhibits 18-45). Petroleum based solvents used in the formulation of adhesives and glues was reported to vary from 0.3 percent to 3 percent (exhibits 18-26), while the finished products and other products such as paints, waxes, floor coatings, and printing inks, normally contain benzene well below 0.1 percent. The benzene content of gasoline was reported as covering a range from 0.5 to 3.5 percent with most samples containing less than 2.0 percent benzene (tr. 344). The American Petroleum Institute submitted results of analyses for benzene on 1,007 samples of crude oil, liquid condensate, natural gas liquids, and gas plant streams. A summary of this data reveals 49 percent of the samples containing less than 0.1 percent benzene, 34 percent containing between 0.1 and 0.5 percent benzene, 10 percent containing between 0.5 and 1.0 percent benzene, 5 percent containing between 1.0 and 2.0 percent benzene, and 2 percent of the samples containing greater than 2.0 percent benzene (PC 81). Rohm & Haas Co. reported that none of their 2,768 products, primarily synthesized organic chemicals, contained greater than 0.1 percent benzene and that benzene was an unintended contaminant in all but 2 of those products (exhibits 18-31).

(4) WHAT IS THE CURRENT PERCENTAGE (OR RANGE OF PERCENTAGES) OF BENZENE IN OTHER SOLVENTS COMMONLY USED AS SUBSTITUTES FOR BENZENE SUCH AS TOLUENE, XYLENE, HEXANE, AND SOLVENT NAPTHAS

Data provided on this issue came primarily from companies not using benzene as a raw material but using materials such as toluene and xylene and other solvents contaminated with benzene. It was indicated, however, by the rubber manufacturers and adhesives and sealant manufacturers, that reformulation or substitution of materials containing no benzene would be infeasible and could possibly diminish the integrity of the final product (tr. 101, 213, 254, 315).

The benzene levels reported in other solvents were somewhat varied, again due to different suppliers, process conditions and equipment used in their manufacture. As a result, it is difficult to identify specific percentages of benzene content in substitute substances with any degree of accuracy. For example, the Adhesives & Sealant Council, Inc., reported that members whose hexane suppliers are located on the west coast show benzene levels of 0.3 percent or higher, while members in other parts of the country purchase hexane with benzene content typically below 0.1 percent. Ranges of benzene impurity reported by the Council include hexane 0.001-2.3 percent; toluene 0.005-0.24 percent; rubber solvent up to 1.0 percent; naptha 0.1-1.0 percent; and mineral spirits up to 1.0 percent (exhibits 18-45). The National Association of Printing Ink Manufacturers, Inc., indicated the following range of benzene content: heptane 0.1 percent-0.75 percent; heptane ("aromatic free") 0.01-0.02 percent; toluene 0.02-0.1 percent; lactol spirits 0.02-0.1 percent; xylene 0.15 percent; and aliphatic hydrocarbon blend 0.01 percent to 0.02 percent (exhibits 18-83). Other participants reported benzene at or below the 0.1 percent level in toluene, xylene, hexane and solvent napthas (exhibits 18-15, 28, 35, 38, 39, 46, 47, 58, 69, 88) while others reported levels in excess of 0.1 percent (exhibits 18-35, 39, 61, 70, 84,

90) with one report of the benzene content of toluene to be 15 percent (exhibits 18-61).

(5) TO WHAT LEVELS CAN THE PERCENTAGE OF BENZENE BE FEASIBLY REDUCED

Those participants, such as the rubber manufacturers and the adhesives and sealant manufacturers, who obtain their solvents from other sources, could not provide any detailed feasibility assessment since they did not have knowledge of the technological potential of their suppliers to reduce the percentages further than present levels. Further complications involved the refusal of solvent suppliers to guarantee a specific benzene level and the fluctuating benzene content found in a given solvent from supplier to supplier. Some suppliers appear reluctant to certify particular solvents since they have not designed their processes with benzene content specification as a consideration. The Manufacturing & Chemists Association testified that a feasibility assessment can be made only after their determination of the benzene content of streams and products is complete (tr. 286). Solvent purchasers generally indicated that, if the solvent industry is capable of reducing the percentage of benzene over some period of time, they would support a graduated exemption setting lower acceptable levels in the future to coincide with the technological ability of the solvent industry to deliver those percentages in dependable volume shipments sufficient to maintain production and employment (exhibit 18-41, 80).

The only specific projection relative to benzene content reduction was in terms of costs. Texaco estimated that benzene reduction in their refinery streams from present levels to 1.0 percent would cost $85 million, a reduction to 0.5 percent would cost $508 million, and a reduction to 0.2 percent would cost $1,381 million. Detailed analysis of how these figures were arrrived at however, was not made available (exhibit 18-48). Another study, which addressed the economic impact of reducing benzene content, is the Arthur D. Little study on gasoline, prepared for EPA in February of 1978 (exhibit 12b).

(6) WHAT AIRBORNE CONCENTRATIONS OF BENZENE RESULT FROM THE PERCENTAGE OF BENZENE IN EACH PRODUCT

Comments and testimony presented on this issue generally revealed that in the industrial setting the benzene content of the liquid mixture plays only a part in the resultant airborne concentration to which employees may be exposed. The evidence regarding the other factors affecting airborne concentration are discussed under issue 7.

Monitoring data submitted to the record has provided a reasonable description of expected exposure levels in the various industrial segments affected by the proposed amendment. As previously discussed, Dr. Hervey Elkins submitted calculations indicating that a 0.5 percent benzene content in liquid mixtures would appropriately be consistent with a 1 ppm permissible exposure limit. The monitoring data submitted tends, for most all cases, to support Dr. Elkins' calculations. For example, General Tire & Rubber Co. submitted data for tire building operations which indicated resultant benzene exposures from rubber solvents containing greater than 0.5 percent benzene did exceed 1 ppm, while solvents with benzene content below 0.5 percent did not (exhibit 18-41). Exposures reported by B. F. Goodrich resulting from up to 0.3 percent benzene content indicate that the companion air levels of benzene were below 0.5 ppm in 95 percent of the cases and only one out of 255 samples was as high as 1.1 ppm (exhibit 18-75). While the Goodyear data tended to suport the proposition that exposure levels, in practice, will generally not exceed 1 ppm with low benzene content liquid mixtures, Goodyear's data from one tire manufacturing plant using from 0.263 to 0.280 percent benzene content rubber solvents indicated exposures between 1.11 and 1.98 ppm. Goodyear attributed these exposure levels to inadequate ventilation since other monitoring data they submitted from other tire building plants using up to 0.4 percent benzene rubber solvents showed exposure levels not in excess of 0.4 ppm. The adhesive and sealant manufacturers reported that, with liquid mixtures containing

up to 1.0 percent benzene, exposure levels never exceeded 1 ppm (exhibit 18-45). Printing ink manufacturers submitted data indicating that, while solvents used contained in some cases in excess of 0.1 percent benzene, exposure levels never exceeded 0.3 ppm (exhibit 18-83). DuPont provided results of tests from paint spraying operations showing that the use of liquid mixtures of 1 percent benzene will not result in airborne concentrations of benzene greater than 5 ppm, in most cases less than 0.5 ppm. Tests were performed with DuPont topcoat paints with 0.05 percent, 0.1 percent, and 1.0 percent benzene added. Benzene was intentionally added to the paints in an attempt to correlate benzene levels in the liquids with airborne benzene concentrations. The highest benzene level obtained was 4.3 ppm with a 1.0 percent benzene spike. Averaged over an 8-hour day, DuPont estimates that normal spraying operations with nonspiked paint will result in employee exposures below 1 ppm. Other DuPont data involving handling of 0.2 to 4.3 percent benzene in gasoline and 0.19 to 0.45 percent benzene in a p-xylene process stream resulted in time-weighted averages up to 0.38 ppm and 0.15 ppm respectively (exhibit 18-39).

Edison Electric Institute reported than exposures resulting from handling fuel oils containing 0.003 to 0.005 percent benzene resulted in exposures less than 0.2 ppm (exhibit 18-56). Husky Oil Co. reported refinery streams with 0.71 percent benzene and finished gasoline with 0.35 percent benzene as producing exposures of less than 0.11 ppm and 0.042 ppm respectively (exhibit 18-64). Earlier data submitted by NIOSH indicated that fuel oil containing less than 0.1 percent benzene gave rise to benzene concentrations of 60 ppm under conditions of elevated temperature, confined space and possibly inadequate ventilation. NIOSH indicated, however, that the sampling was done with detector tubes which are relatively inaccurate and subject to numerous interferences. (tr. 753-755, July 25, 1977, hearing)

While other participants (exhibits 18-24, 35, 49, 84, 87) supported the proposition that benzene levels in liquid mixtures greater than 0.1 percent would still not generally produce exposures to benzene above 1 ppm, some

participants provided data to the contrary. The United Rubber, Cork Linoleum & Plastic Workers of America (URW) (exhibit 18-33) referenced testimony presented by Dr. Robert T. Harris, of the University of North Carolina at the public hearing on the proposed benzene standard (docket H-059), in which Dr. Harris stated that bulk solvent percentages of benzene from 0.5 to 1.07 percent can produce exposure levels below and above 1 ppm, some as high as 12 ppm. The reliability of the results of this study were questioned by Dr. Curtis Smith of the Manufacturing Chemists Association who indicated that the findings as to the presence of benzene in the ambient air could have been artificially high because of interference of ketones which are present in the ambient air around rubber plants (tr. 299). URW submitted other exposure data from an Armstrong tire manufacturing facility (the "Harvard study") also indicating exposure levels above 1 ppm with solvents containing low levels of benzene. A number of participants, including Armstrong, questioned the reliability of the Harvard study (PC 89, 90, 91, 92, 105). Armstrong commented on the study as follows:

> The report itself makes it clear that no analyses were made by the Harvard study during the week of January 9, 1978, with respect to the bulk samples. Reference is made to the analysis by the Armstrong laboratory in June 1977 that benzene in Texol at that time was less than 0.1 volume percent. More than 6 months elapsed between such sampling of the solvent and the air sampling. It is to be regretted that in the only monitoring done to date with respect to an Armstrong facility, and a very limited sampling at that, the monitoring was not accompanied by an analysis of the solvent in use at the time of such monitoring.
>
> In addition, the sample period did not cover the full 8-hour period for computation of the time weighted average (TWA). The TWA, in fact, was estimated from a sampling time of approximately 2 to 3 hours.

> NIOSH in its Occupational Exposure Sampling Strategy Manual, DHEW (NIOSH) Publication No. 77-173 (January 1977) is critical of partial period sampling. The Manual states, at page 40, that the "sampled portion of the period should cover at least 70 percent to 80 percent of the full period." Indeed, in discussing the validity of a 6-hour TWA exposure average as compared with an 8-hour TWA standard, the Manual states, at page 41, that "[t]his type of measurement should be avoided if possible." It therefore follows that a significantly shorter period is even less valid (PC-91).

Other participants, sharing reservations relative to a particular percent exemption, did so on the grounds that exposure measurements from liquid mixtures containing 0.1 percent or less benzene did or could theoretically produce airborne concentrations of benzene in excess of 1 ppm or that variables such as ventilation, liquid temperature, work practices, etc. affected resultant benzene airborne concentrations to too great an extent to confidently rely on only benzene content for limitation of employee exposures (exhibits 18-32, 61, 72, 79, 92, 94, PC-S-8).

(7) TO WHAT EXTENT DO VARIOUS FACTORS, SUCH AS TEMPERATURE, DILUTION WITH AMBIENT AIR, WORK FACTORS, NATURE OF OPERATIONS, ETC., AFFECT THE RELATIONSHIP BETWEEN THE PERCENTAGES OF BENZENE IN THE VARIOUS PRODUCTS AND RESULTING AIRBORNE CONCENTRATIONS, AND SHOULD ANY EXEMPTION BE LIMITED TO THE USE OF THESE PRODUCTS UNDER PARTICULAR CIRCUMSTANCES

As previously indicated, most participants agreed that factors other than benzene content can play a significant role in resultant airborne concentrations of benzene. Goodyear stated that ventilation, climate, work habits, etc., would definitely affect the airborne concentration of benzene, and submitted monitoring data from an older tire manufacturing facility and two newer plants for

comparison. The two newer facilities using rubber solvent containing 0.4 percent and 0.2 to 0.3 percent benzene experienced airborne concentrations of benzene at 0.45 and 0.25 ppm respectively. The older tire plant using rubber solvent with 0.263-0.280 percent benzene experienced airborne concentrations of 1.11 to 1.98 ppm. Goodyear attributed this discrepancy to inadequate ventilation in the older tire manufacturing facility. Goodyear further indicated that, while they could not determine an exact correlation from their data, variables other than benzene content could cause up to an 80 percent variance in resulting airborne concentrations. (PCS-8). Other participants provided either theoretical or actual data indicating exposures greater than 1 ppm from low benzene content mixtures used under conditions of confined space, inadequate ventilation, elevated temperatures etc. (exhibit 18-32, 92). URW submitted previous testimony of Dr. Robert T. Harris presented at the public hearing on the proposed benzene standard (docket H-059) in which Dr. Harris stated that "* * * the lower the benzene content of the solvent, the lower the potential for exposure, but a low benzene content of solvent alone does not assure that a particular air concentration will not be exceeded" (exhibit 18-33).

As mentioned previously, Dr. Hervey Elkins submitted calculations estimating that a 0.5 percent benzene content would not normally be expected to produce airborne concentrations of benzene greater than 1 ppm. Dr. Elkins addressed the affect of other factors on his calculations:

> It is self-evident that the factors mentioned (temperature, ventilation, work practices, nature of operations) will affect the relationship between the percentage of benzene in a liquid product and the resulting concentration of benzene vapor in the air. Important factors not mentioned include the quantity of substance consumed or processed, the area of the liquid surface which is exposed to the air, and the vicosity of the liquid.
>
> The exemption percentages proposed (i.e., 0.5 percent to meet 1 ppm) were based on rather severe

conditions: complete or free evaporation of the benzene and other volatile ingredients, limited only by the provision that the permissible limits of the vapors of the other components of the liquid must not be exceeded.

With some high boiling liquids, such as heavy oils and tars, there is little evaporation of the base material, even when heated to temperatures well above the boiling point of benzene. In theory, processes employing such materials at elevated temperatures and with large surface areas exposed (as might occur in certain coating or impregnating processes) could produce concentrations of benzene vapor in the surrounding air in excess of the postulated permissible exposure levels, even when the concentration of benzene in the liquid is less than the limits recommended above.

On the other hand, handling and processing such liquids in enclosed or partially enclosed spaces, with limited exposure of liquid surfaces to air, and at temperature such that the material is not highly fluid, would result in benzene concentrations well below the postulated permissible exposure levels, even when the percentage of benzene in the liquid is in excess of the limits recommended above.

For the sake of simplicity, it is recommended that * * * the 0.5-percent exemption percentage be applied if the airborne permissible exposure limit is 1 ppm—with the proviso that if operations involving heating of the liquids and exposure of large surface areas are carried out, at least a one time monitoring of the area of benzene in air be done, if the benzene content of the liquid exceeds 0.1 percent. (PC-82)

API argued in its post-hearing brief that the record evidence does not identify a specific percentage of benzene which will guarantee that a given PEL will not be exceeded under all work environments and that, therefore, any percentage exemption must also take account of the roles of many other controlling factors. API further stated that, regardless of the benzene content in their streams, the nature of their oil and gas operations is the most important factor in considering potential exposures and need for regulation of their segment of the industry. API witness Dr. William G. Domask testified that:

> It is evident from the data and information presented here that well-maintained, closed-system operations in general represent a low risk for exposure to benzene.
>
> Specifically, petroleum production, pipeline, and marketing personnel air monitoring data reflect a very low risk of exposure to benzene vapor at all concentration levels of benzene in the liquids handled by these segments of the industry.
>
> Similarly, data for the closed-system portions of refining operations indicate a very low level of exposure to benzene (PC-81).

While many other participants addressed this issue and acknowledged the significance of factors other than benzene content relative to resultant airborne concentrations of benzene, there were no recommendations relative to a practical translation of requirements for a homogeneous regulatory conclusion which would give full weight to those factors.

(8) TO WHAT EXTENT, AND FOR WHICH LIQUID MIXTURES, ARE BENZENE-FREE SUBSTITUTES AVAILABLE

Most industry participants argued that benzene-free substitutes are not commercially available, are not suitable for their process due to incompatibility with other materials and existing air pollution control systems and methods, are economically prohibitive, or would reduce product performance (exhibit 18-15, 21, 39, 41, 54, 80, 90, 109). The Public Citizen Health Research Group argued that benzene substitutes are available (exhibit 18-94).

However, the record indicates that "benzene-free" substitutes are not generally available for the majority of industrial uses.

(9) IF LIQUID MIXTURES OF SPECIFIED PERCENTAGES ARE EXEMPT FROM THE OTHER PROVISIONS OF THE BENZENE STANDARD, SHOULD THEY NEVERTHELESS BE SUBJECT TO THE LABELLING REQUIREMENTS OF THE STANDARD. CONVERSELY, IF SUCH MIXTURES ARE NOT EXEMPT FROM THIS STANDARD, SHOULD THEY BE EXEMPT FROM THE LABELLING REQUIREMENTS

Industry participants indicated that some relief from the labeling requirements was necessary. They argued that, without some labeling exemption, liquids which contain trace amounts of benzene would require cancer hazard labels. They objected to such labeling on the following grounds: lack of associated health hazard requiring warning; economic burdens; uncontrolled use of warning labels dilutes effectiveness of warning messages; and, the ubiquitous nature of benzene in petroleum distillates. The recommendation of industry participants was that any liquid mixture exemption of a specified percentage should include an exemption from the labeling requirements (exhibit 18-21, 29, 31, 37, 41, 42, 69, 71, 72, 79, 83).

DuPont testified that, without a labeling exemption to allow additional time to clear existing inventories carrying levels of 0.1 to 1.0 percent benzene, the cost of locating already packaged containers and labeling them would run to about $31 million (tr. 317). DeSoto, a manufacturer of paints, industrial coatings, detergents, furniture and fireplace accessories, estimated their cost of labeling present inventory at $700,000 (exhibit 18-43). Another paint and coatings manufacturer, Pratt & Lambert, Inc., estimated a current inventory of 1.4 million containers, which without an exemption, would cost $700,000 to label (18-44).

(10) OTHER RELATED ISSUES

(a) *Monitoring feasibility.* A number of industry participants provided data indicating potential difficulties in obtaining industrial hygiene and analytical services. The cost burden and reported lack of monitoring service capabilities in some locations which would result if some exemption were not provided to part of the industry, would render compliance with parts of benzene standard impossible (exhibit 18-1, 3, 9, 12, 20, 37, 39, 65, 68, 82, 87).

The Manufacturing Chemists Association stated that analysis for benzene requires equipment which is expensive and which must be operated by specialists. They maintained that, due to interference from other substances, multiple gas chromatography analyses on a single product or use of mass spectrometric equipment together with gas chromatography, available only in large laboratories, are required to produce good analytical results (PC-103). NIOSH addressed the problem of interferences in a post-hearing submission (PC-88) in which they report that work by Levadie and MacAskill, "Analytical Chemistry," 48, 76, 1976, and by Esposito and Jacobs, "American Industrial Hygiene Journal," 38, No. 8, 401, 1977, describes the modifications to the NIOSH sampling and analytical methods for benzene, S311, necessary to solve the problem of interferences arising from ketone materials in the analysis for benzene. NIOSH also noted that the price of mass spectrometer systems has declined steadily over the last five years. It is NIOSH's position, therefore, that benzene can be identified with confidence using the NIOSH recommended method, that interferences can be handled by simple extraction techniques prior to gas chromatography, that detectors or columns are readily available and within the normal financial limitations of most commercial laboratories, and that recourse to mass spectrometry is unnecessary.

(b) *Miscellaneous comments.* Due to the unique nature of the motor carrier industry whose employee exposure to benzene is occasional and then only minimal, the National Tank Truck Carriers, Inc. recommended that if OSHA has any concern over motor carrier's employee exposure to benzene, OSHA should petition the Department of Transportation to develop regulations, thus avoiding regulatory imposition by another agency over an already regulated sector (tr. 414).

The National Agricultural Chemicals Association argued that OSHA has no authority to require labeling of

pesticide products and no need to duplicate or interfere with the labeling controls imposed by the Environmental Protection Agency (exhibit 18-53).

The National Retail Merchants Association urged an exemption from the standard for retail stores since employee exposure in those stores is from consumer goods which are in closed containers. They also argued that, while paint cans are opened for mixing and coloring, the brief and intermittent nature of the operation would not result in sufficient benzene exposures to merit regulation. NRMA further stated that the standard should not apply to existing inventories since retailers would then be unable to sell products they already owned (exhibit 18-37).

V. Analysis and Feasibility

OSHA has concluded that it is appropriate to amend the permanent benzene standard to provide for a percentage exclusion. Specifically the agency has exempted from all the provisions of the standard for the first 3 years following the effective date of this amendment, liquid mixtures containing 0.5 percent or less benzene, and thereafter liquid mixtures containing 0.1 percent or less benzene. Further, OSHA has exempted from the labelling requirements liquid mixtures containing less than 5.0 percent benzene which are already packaged.

OSHA recognizes that the scope of the permanent benzene standard (29 CFR 1910.1028), unamended, is so broad as to encompass work place operations utilizing liquid mixtures with any amount of benzene however small (tr. 30). OSHA's view that there is no level of benzene exposure that is without some attendant health risk remains unchanged. However, because of the ubiquitous nature of benzene, i.e., its presence in a myriad number and type of worksites (benzene is a contaminant in most, if not all petroleum-based liquid mixtures), OSHA believes that it is proper to focus industrial hygiene and medical resources on those operations with higher exposures and which present the greatest potential risk to worker health. This decision is in accord with the evidence developed during the recent rulemaking which

revealed the need to and appropriateness of limiting the scope of the standard.

The mechanism chosen to effectuate this relief must in OSHA's view be consistent with the intent of the permanent standard, which is to minimize the risk to worker health to the greatest extent feasible. The framework within which the agency has examined this issue was articulated by the Director of OSHA's health standards programs, Grover C. Wrenn, at the outset of the informal hearing:

> Since the standard itself establishes a permissible exposure limit for benzene, we would certainly endeavor to set an exemption which assured that employees exposed to materials exempt from coverage under the regulation are subject to no greater exposure than employees who are subject to the provisions and protection of the standard (tr. 16).
>
> And one of the questions that was raised in the earlier rulemaking and one of the questions that is raised here is the question of the likelihood that exempting any particular category of materials from regulation, under the benzene standard—the likelihood that that exemption would provide a basis for being confident that workers involved with those exempt materials would not be exposed in a manner that was intended to be avoided by the benzene regulation (tr. 16).

The agency has considered and reviewed several approaches for limiting the scope of the permanent benzene standard suggested by participants to the rulemaking. These options included a single percentage exclusion applicable to all provisions of the standard, as was set forth in OSHA's proposed amendment in the Federal Register notices of March 28, 1978 (43 FR 12890) and April 28, 1978 (43 FR 18215). Such an approach was recommended by many participants as cited under the discussion of issue 1. Another option called for a general percentage exclusion, but with different levels for certain provisions of the permanent standard. This type of amendment, which was suggested by the Rubber Manu-

facturers Association and member companies (Exh. 92), specifically called for a higher percentage exclusion for the dermal and labelling provisions of the standard relative to other sections. A third option was that relief from the standard by based not on a percentage exclusion (with perhaps the exception of the dermal provision) but rather be based upon actual employee exposure levels. This recommendation was made by API, NPRA and member companies and also supported by OCAW (Ech. 104, Tr. 400). A final option would include a general percentage exclusion with the additional proviso that, in the case of severe or unusual work situations, the permissible airborne limits should not be exceeded as determined by monitoring. (Exh 27-C.1, PC-82)

OSHA has carefully evaluated these and other possible approaches and, based upon a review of the evidence and views contained in the rulemaking proceedings, has concluded that a percentage exclusion amendment applicable to all provisions of the standard most adequately satisfies, for regulatory purposes, the dual intention of appropriately limiting the scope of the permanent benzene standard while not exposing exempted employees to greater exposures than employees covered by the standard.

The record evidence of percentage exclusion rulemaking establishes, as shown in the preceding discussion of issues, that a variety of liquid mixtures with small or "trace" amounts of benzene generally result in exposure levels below the permissible exposure limit of the permanent benzene standard in a wide variety of industries. OSHA has determined, by examining the relationship of the percentages of benzene to resultant exposure levels, that generally an appropriate percentage exclusion can assure that employees who would be exempt from the coverage of the benzene standard are not exposed above the level set in the standard (tr. 16). Furthermore, it is OSHA's view that a percentage exclusion will encourage employers to act to reduce the amount of benzene present in liquid mixtures utilized in their workplaces or present in their products and, therefore, reduce the potential health hazard to employees. The record clearly establishes that, since publication of the permanent benzene stand-

ard, paint manufacturers and other solvent users have already examined the need for benzene in their liquid mixtures, and have made extensive efforts to obtain solvents with lower percentages of benzene. OSHA believes that an appropriate percentage exclusion will be an incentive to many other employers to reduce benzene levels and thus minimize the leukemia and other health risks to their employees.

In arriving at the conclusion that an "across-the-board" percentage exclusion is the appropriate means to afford an opportunity for relief from the standard without subjecting workers to undue risk, OSHA recognizes that factors other than the benzene content of liquid mixtures can act to significantly modify the resulting levels of airborne exposure. Variables such as the nature of work operations and work practices, and quantifiable parameters such as temperature, size of evaporative area, and especially ventilation all have been shown to play an important role. This data thus supports Dr. Harris's earlier conclusions that there is no necessary correlation between the amount of benzene in liquid mixtures and resulting airborne levels. However, defining the parameters and determining the exact combination of factors which significantly increase exposure, a necessary accomplishment for regulation on this basis, is not possible and no witness could suggest means of doing so. Moreover, the preponderance of evidence submitted to this rulemaking (most of which was not available at the earlier rulemaking) manifestly establishes, based on objective sampling data derived from current industrial settings, that for the vast majority of worksites, small amounts of benzene in liquid mixtures do not result in worker exposures above 1 ppm.

An additional reason for not adopting alternative strategies to amend the permanent standard is that the record did not provide evidence for the need to provide different exemption levels for different provisions. Manufacturers of rubber goods argued that an "action-level" concept be applied to the dermal section of the standard because of the infeasibility of performing certain manual operations in their industry without some skin contact

with benzene-containing solvents. However, as was explained in the preamble to the permanent standard, from the point of view of choosing a "safe" level, the permissible exposure limit should be zero (exhibit 3A). In the case of airborne exposure, clearly this was not attainable and their airborne permissible exposure limits established were not "no-effect" levels, rather were based on feasibility considerations. However, with respect to dermal contact, avoidance of skin exposure is feasible for workers in most industrial sectors simply by the use of suitable protective clothing, such as impermeable gloves. OSHA recognizes that in tire-building, the record evidence shows that at present there are no suitable methods available to prevent skin contact with solvents containing a small amount of benzene. However, the record evidence establishes that rubber solvents with 0.5 percent benzene, which are suitable for use in tire operations, are already available in sufficient quantities. Accordingly, the exemption of 0.5 percent liquid mixtures from all the provisions of the benzene standard, will substantially relieve the feasibility problems in tire building operations. Furthermore, the 3 year stepdown provision of the amendment from 0.5 to 0.1 percent exclusion levels will allow time for increased production of solvents containing lower amounts of benzene and for development and evaluation of alternative methods of compliance with the standard's dermal provision.

Some participants suggested that a higher exemption level apply to labeling (Tr. 68, 188). OSHA does not agree. The labeling requirement of the permanent standard serves to inform the worker of the hazard associated with working with benzene containing liquid mixtures. Use of a higher percentage exemption for this provision could result in the employee not being apprised of the danger in situations where exposure might be excessive.

API has argued that an "across the board" percentage exclusion is not an effective method by which to amend the standard, and that, in general, an exemption predicated on exposure levels is a better way of dealing with the problem presented by liquid mixtures containing small quantities of benzene (PC 104). While acknowledging

that there are other factors in addition to benzene concentration which may significantly affect airborne exposure levels, OSHA believes that there is sufficient record evidence which demonstrates that with low levels of benzene contamination airborne exposures are generally below the PEL and frequently below the action level. Many participants in the rulemaking also supported this conclusion. Furthermore, API's recommendation that various provisions of the permanent standard be triggered by workers' exposure levels is, to a great degree, already incorporated into the standard by OSHA's use of the action level concept. The objective of the benzene standard is to provide necessary protection to employees from the hazards of benzene exposure, and to this end, the standard imposes upon employers different compliance requirements depending on the level of employee exposure, with minimal requirements imposed where employee exposure is below the action level.

The primary difference between API's suggested use of an "exposure determination" and OSHA's decision reflected in the standard is that API would not require initial monitoring in all cases but rather would rely upon professional judgment to determine whether various provisions of the standard apply. However, it should be noted that API's judgment as to which operations in the petroleum industry have low exposures is based upon objective sampling data submitted to this record; to the extent that such data exists the initial monitoring requirements of the permanent standard may be satisfied.

OSHA recognizes that conditions, such as elevated temperatures, inadequate ventilation, confined space, quantity of material used etc., could in some cases act to produce exposures above the PEL even if the same benzene percentages would in other operations result in exposures less than the PEL. However, as already stated, the record does not provide a sufficient basis upon which to identify and define these variables for regulatory purposes.

The results of monitoring of employee exposure submitted by numerous participants demonstrates that, by and large, the use or presence of liquid mixtures contain-

ing benzene with maximum concentrations of 0.5 percent benzene results in airborne concentrations of less than 1 ppm and frequently less than the action level of 0.5 ppm. However, the low airborne concentrations reported are not necessarily due to the inherent nature of the liquid mixtures utilized (exhibit 18-32), but rather are in part the result of the maintenance and effectiveness of engineering controls to limit exposures. Therefore, maintenance of these low exposure levels can be dependent upon the continued use of engineering controls. This is illustrated by the testimony of Goodyear which shows that, in contrast to the majority of their operations, which indicated that use of solvents containing up to 0.4 percent did not result in exposure levels greater than 0.4 ppm, in one plant with inadequate ventilation, exposures greater than 1 ppm were observed when the solvent utilized contained only 0.26 to 0.28 percent benzene. (PC-S-8). In the case of refineries, although the benzene content of liquid streams may range up to 3.5 percent by volume or higher, the great majority of worker exposures are less than 0.5 ppm (tr. 339-345.) It is evident that such low exposures in the petroleum industry are due to the outdoor setting and, importantly, to the use of closed systems. Although not always explicitly stated, the low exposures measured in some situations, such as the use of benzene-containing solvents by rubber manufacturers, appears to be the result of engineering controls as well as effective work practices.

Close examination of Dr. Elkins' calculations also indicates that a percentage exclusion level of 0.5 percent may not be sufficiently conservative. His calculated average of all values of benzene percentage limits, which was consistent with exposures of 10 ppm (the time-weighted average PEL of the previous standard) was approximately 1 percent when utilizing a total upper limit concentration of 500 ppm for petroleum distillates (PC-82). If the same underlying assumption is used (rather than utilizing NIOSH's recommended 350 milligrams per cubic meter which is not presently in effect) to calculate the percentage of benzene in a liquid mixture consistent with the 1 ppm PEL of the permanent standard, the mean value

would decline approximately 10-fold or to a level of about 0.1 percent benzene in liquid mixtures (tr. 393-94). Elkins' data takes into account abnormal worst case work situations. Therefore, a 0.1 percent exclusion level should maintain workplace levels at below the permissible exposure limit even in the abnormal work situations cited by Dr. Elkins.

In adopting an across the board exclusion level, two problems arise: (1) In some cases, where the benzene stream content is in excess of the prescribed percentage and the standard there applies, exposures may well be below the PEL or action level; and (2) in certain cases, the exemption of work operations where the benzene content of liquids are below the prescribed exclusion level may produce exposures in excess of the PEL.

In the first case, although exposures may be low, the potential exists for excessive exposures, such as in the case of leaks, spills and process upsets from enclosed systems. The agency believes, that because of this potential, the requirements of the permanent standard are necessary for the protection of employees working in such areas. In the second situation, this agency recognizes that adoption of a 0.1 percent exclusion level does not, in all cases, assure that resulting airborne exposures will necessarily not exceed the action level of 0.5 ppm or even the permissible exposure limit of 1 ppm. OSHA further recognize that 0.5 percent factors other than the percentage of benzene may become more significant in determining exposure levels. However, the record does not indicate that exposures greater than 1 ppm have been demonstrated to be commonly found in existing industrial situations where benzene levels in liquid mixtures are less than 0.1 percent.

Ideally, the percentage exclusion level chosen should be so low as to assure that in all instances, the PEL will not be exceeded. Participants representing users of benzene-containing solvent mixtures who recommended exemption levels of 0.5 to 1 percent, conceded that they would readily utilize solvents containing even less benzene if they were available. While some participants from industry testified that they were able to obtain solvents with less than

0.1 percent on a regular basis, the record evidence demonstrates that for most industrial processes liquid mixtures containing 0.1 percent or less benzene are not commercially available at this time. Thus, the percentage exemption level chosen by OSHA for amendment purposes must take into account the feasibility of supplying large volumes of liquids containing less than a specific amount of benezene to a multitude of industrial users.

Testimony from the producers of liquid mixtures which contain varying amounts of benzene indicate that the benzene which is present is there only as a contaminant and generally is not intentionally added to produce a particular property in the formulations or products. Furthermore, while it appears to be impossible to exclude very small amounts of benzene in many of these products MCA witnesses observed that the technology currently exists to produce liquid mixtures containing 0.1 percent or less of benzene (tr. 278). However, their testimony also demonstrated that reduction of benzene content to the 0.1 percent level is not a simple undertaking. Because benzene is a widespread contaminant in most petroleum-based liquid products, some time will be required to complete testing to determine the current levels of benzene in their products. Once this process is complete, industry will require an additional period of time to implement appropriate process changes which would assure low level benzene content. This latter phase is in some instances complex, as the percent of benzene is dependent upon existing production factors, such as differences in crude runs, the nature and efficiency of individual refinery processes and the specific balance of final products produced at a given point in time. In addition, it appears that market conditions may also be a significant factor determining the degree to which benzene has been extracted from petroleum-based streams. The record also indicates that only in the recent past have producers of benzene-containing liquids given significant consideration to the benzene content of their products (tr. 286).

Two studies addressed the economic feasibility of reducing benzene content in certain liquid mixtures (exhibit 18-48; exhibit 12B). However, it is OSHA's view that the

cost of reducing benzene content are not attributable to this percentage exclusion amendment. Reducing the benzene content in liquid mixtures in order to avoid coverage by the benzene standard is an option which the employer may exercise; it is not a requirement of the benzene standard that he do so. Employers may prefer to comply with the permanent standard, particularly where their employees are exposed below the action level, in which case the employer would need only to conduct initial measurement, record that measurement and train his employees. Since the standard does not compel reduction of benzene content, it is OSHA's view that costs involved in reducing the percentage of benzene in a liquid are not a consideration in this amendment.

Other than indicating that considerable time would be required to complete analysis of benzene content of their products, (exhibit 18-87) industry did not provide estimates nor specific recommendations as to the time frames required to effect production changes in order to produce liquid mixtures containing 0.1 percent of less of benzene in sufficient quantity to meet the anticipated needs of downstream users. Because of the above considerations, industry participants felt that OSHA should not at this time adopt a percentage exclusion at the level of 0.1 percent as proposed by the agency. However, it should be noted that the proposed permanent regulation, which did indicate that the agency was considering a 0.1 percent exclusion level, was published over a year prior to the most recent rulemaking. Review of the evidence submitted indicates that while not commercially available on a sufficiently large basis, mixtures with 0.1 percent or less benzene content have been produced and are available on a limited basis and are compatible with most processes requiring such mixtures.

The record evidence further demonstrates that mixtures with a benzene content of up to 0.5 percent are presently available in sufficient quantity to satisfy the needs of affected industrial segments and that suppliers of these liquid mixtures are attempting to reduce the benzene content still further. OSHA has, therefore, concluded that

0.1 percent benzene content can be feasibly attained on a commercial basis at some point in the future.

It is the judgment of the Agency that a period of 3 years is a sufficient and reasonable allowance for development and implementation of means and methods necessary for production of adequate supplies of 0.1 percent benzene content mixtures. Along with the consideration of feasibility, the record evidence indicating a relative lack of suitable "benzene-free" substitutes, dictates the need for providing a period for implementation which would meet the anticipated demand for solvents containing low percentages of benzene. In addition, the 3-year period before the stepdown to the 0.1 percent level, will allow those users of benzene-containing liquid mixtures to test for product integrity before commencing reformulation on a large-scale basis.

By adoption of the 0.5 percent exclusion level initially, many employers engaged in crude oil and gas production activities will be provided relief from all provisions of the permanent standard. The agency is aware that, by decreasing the exclusion level to 0.1 percent after 3 years, many of the facilities and employees in the petroleum production sector will then be covered by the standard. It is also recognized that since benzene is a naturally-occurring constituent of crude oil and natural gas, its level is not under the control of the employer. However, since compliance requirements of the permanent standard are directly related to the exposure level of the employees, and since it has been demonstrated that exposure levels of personnel in oil and gas production are generally below the action level of 0.5 ppm, the requirements of the permanent standard are minimal beyond the taking of an initial representative exposure measurement. The 3-year delay prior to the step-down to the 0.1 percent level also provides additional time for employers to obtain the required sampling information.

This amendment also exempts from the labeling requirement, liquid mixtures containing 5.0 percent or less benzene if the liquid mixture is already packaged on the effective date of this amendment. Record evidence indicates that there may be a large number of containers

already in the channels of commerce, particular consumer products, that would be subject to the labelling requirement if such an exemption were not provided. While the labelling of existing containers may be possible, it is also clear that it would require a substantial effort. Thus, imposition of the labelling requirement for liquid mixtures already packaged might well result in an excessive disruption of the commercial framework. For liquid mixtures packaged after the effective date of these amendments, the 0.5 percent exemption applies. Those employers who utilize or manufacture liquids containing 0.5 percent or less benzene will have 3 years to meet the labelling requirements, and may be exempt entirely if in that period of time they can reduce benzene concentrations below 0.1 percent.

OSHA has chosen a level of 5 percent or less benzene (by volume) contamination as the boundary for exempting liquid mixtures already packaged. Evidence developed during the rulemaking indicated that there may be some products already in the channels of commerce which may contain benzene well in excess of 1 percent and which may not have been analyzed and which would be difficult to track down. In addition, the 5 percent level chosen is similar to the requirement of the Consumer Product Safety Commission which, under the Federal Hazardous Substance Act Regulations (16 CFR 1500.14(a)(3)), mandates that products with 5 percent or more benzene receive a special label. In products with an average molecular weight similar to that of benzene, 5 percent by volume is similar to 5.0 percent by weight.

It is the agency's judgment that much of the National Tank Truck Carrier's Association's concerns regarding the imposition of the provisions of the permanent standard on their members will be substantially relieved as users of various liquid mixtures demand products containing less than the prescribed percentage levels of benzene. In the absence of the exercise of authority by the Department of Transportation in this matter, 1910.1028, as amended, applies to this industry (sec. 4(b)(1)).

EFFECTIVE DATE

This amendment is effective immediately on June 27, 1978. Since this amendment is a rule granting an exemption, the Administrative Procedure Act (5 U.S.C. 553) does not require a 30-day period before the amendment becomes effective. Section 533(d)(1) of the APA exempts rules which grant an exemption or relieve a restriction from the requirement that publication of a substantive rule be made not less than 30 days before its effective date. This amendment exempts from the permanent benzene standard operations utilizing liquid mixtures of 0.5 percent or less (0.1 percent or less after 3 years). Without this amendment, all employers with such operations would be required to implement the various protective requirements of the permanent standard, such as initial monitoring, training and recordkeeping. The amendment relieves them of this burden.

In addition the amendment exempts from the labelling requirements liquid mixtures which are already packaged in containers and which contain 5 percent or less benzene. Such containers would otherwise be subject to the labelling requirements of the standard. The amendment, therefore, relieves employers of the requirements to label these containers.

Accordingly, these amendments are effective June 27, 1978. As with the other operations exempted from § 1910.1028, the benzene standard contained in Table Z-2 of § 1910.1000 will continue to apply to the operations exempted by the amendments.

Upon the publication of this amendment, the limited administrative stay adopted by OSHA in conjunction with this rulemaking (43 FR 12891) is no longer in effect.

VII. AUTHORITY

This document was prepared under the direction of Eula Bingham, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Avenue N.W., Washington, D.C. 20210.

Accordingly, pursuant to section 4(b)(2) and 6(b) of the Occupational Safety and Health Act of 1970 (84 Stat. 1592, 1593, 29 U.S.C. 653, 655), the specific statutes referred to in section 4(b)(2), Secretary of Labor's Order No. 8-76 (41 FR 25059), and 29 CFR Part 1911, Part 1910 of Title 29, Code of Federal Regulations, is hereby amended by adding new paragraphs (a)(2)(iii) and (k)(2)(iii) to 29 CFR 1910.1028.

Signed at Washington, D.C., this 21st day of June 1978.

EULA BINGHAM,
Assistant Secretary of Labor.

Part 1910 of Title 29 of the Code of Federal Regulations is hereby amended by adding a new paragraph (a)(2)(iii) and a new paragraph (k)(2)(iii) to § 1910.1028 to read as follows:

§ 1910.1028 Benzene.

(a) *Scope and application.* * * *

(2) This section does not apply to:

* * * *

(iii) Work operations where the only exposure to benzene is from liquid mixtures containing 0.5 percent (0.1 percent after June 27, 1981) or less of benzene by volume, or the vapors released from such liquids.

* * * *

(k) *Signs and labels.* * * *

(2) The employer shall assure that caution labels are affixed to all containers of benzene and of products containing any amount of benzene, except:

* * * *

(iii) Liquid mixtures containing 5.0 percent or less benzene by volume which were packaged before June 27, 1978.

(Secs. 4, 6, 84 Stat. 1593 (29 U.S.C. 653, 655); Secretary of Labor's Order 8-76 (41 FR 25059); 29 CFR Part 1911.)

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